Supreme Court of the United States

OCTOBER TERM, 1971

No. 71-666

UNITED STATES OF AMERICA, APPELLANT,

v.

GLAXO GROUP LIMITED, AND IMPERIAL CHEMICAL INDUSTRIES, LIMITED

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

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RELEVANT DOCKET ENTRIES

3/4/68	Complaint filed
3/28/68	Motion of defendant Glaxo to quash service of process
4/22/68	Oral argument before Judge Curran to quash service
4/29/68	Answer by defendant ICI
4/30/68	Order of Judge Curran denying motion to quash service
5/2/68	Answer by defendant Glaxo
6/25/68	Order of court of appeals denying defendant Glaxo's application for permission to appeal under 28 U.S.C. 1292(b)
9/23/68	Government motion for leave to amend complaint
10/14/68	Glaxo opposition to motion to amend
10/15/68	ICI opposition to motion to amend
10/15/68	ICI motion for judgment under Rule 12(c) or 56 on patent validity issue
10/30/68	Government cross-motion under Rule 56 for partial summary judgment that ICI patent is invalid
10/31/68	Government motion under Rule 56 for partial summary judgment against ICI (ICI-AMHO agreement)
10/31/68	Government motion for assignment of case to single judge for all purposes
11/8/68	Cross-motion of defendant ICI under Rule 56 for partial summary judgment (mootness)
11/8/68	Opposition by defendant ICI to motion for single judge
11/12/68	Opposition by defendant Glaxo to motion for single judge

12/2/68	Order of Judge Curran denying motion for single judge
1/23/69	Oral argument before Judge Gasch on (i) summary judgment motion on restraint on alienation, (ii) cross-motion of ICI for summary judgment on same issue that complaint should be dismissed; (iii) ICI's motion to dismiss or for summary judgment on patent validity; and (iv) motion by United States to amend the complaint
6/4/69	Order of Judge Gasch on motions for summary judgment
6/13/69	Government motion under Rule 56 for partial summary judgment against Glaxo
7/24/69	Order denying government cross-motion for partial summary judgment that ICI patent is invalid
8/6/69	Opposition by Defendant Glaxo to motion for partial summary judgment and motion by defendant Glaxo to quash service of process
10/20/69	Oral argument before Judge Sirica on motion by United States for partial summary judgment
11/20/69	Order of Judge Sirica granting motion for partial summary judgment and deny motion to quash service
12/3/69	Government motion under Rule 56 for partial summary judgment against defendants
2/5/70	Opposition of defendant ICI to motion for partial summary judgment
2/5/70	Opposition of defendant Glaxo to motion for partial summary judgment
3/24/70	Oral argument before Judge McGuire on motion by United States for summary judgment against ICI on restraint against alienation issue
4/30/70	Order of Judge McGuire granting motion for partial summary judgment

5/20/70	Government motion for entry of final judgment
12/17/70	Oral argument before Judge Gasch on motion for final judgment
6/17/71	Final judgment entered by Judge Gasch
6/28/71	Motion by defendants to clarify judgment
8/12/71	Declaration by court as to judgment
8/16/71	Government notice of appeal
9/20/71	Government notice of appeal
3/21/72	Order dated March 9, 1972, amending final judgment.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,
Department of Justice
Washington, D. C. 20530

PLAINTIFF,

v.

GLAXO GROUP LIMITED
Clarges House
6-12 Clarges Street
London, W.1., England
IMPERIAL CHEMICAL INDUSTRIES LIMITED
Imperial Chemical House
Millbank, London, S.W.1, England

DEFENDANTS.

Civil No. 558-68
Filed: March 4, 1968

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

The United States of America, plaintiff, brings this civil action against the defendants, pursuant to Section 4 of the Sherman Act (15 U.S.C. § 4), to restrain them from violation of Section 1 of the Sherman Act (15 U.S.C. § 1); and it alleges:

I. THE DEFENDANTS

1. The defendant Glaxo Group Limited (hereafter referred to as "Glaxo") is a corporation organized and existing under the laws of Great Britain, with its principal place of business at Clarges House, 6-12 Clarges Street, London, W.1., England. Glaxo had net sales of approximately $175 million in 1966, and total assets of approximately $180 million, as of June 30, 1966. Prior to December 1961, Glaxo was incorporated under the name "Glaxo Laboratories Limited."

2. Glaxo is the owner of the following United States patents (hereafter referred to as "the Glaxo patents"): No. 2,843,527 ("Production of griseofulvin in low nitrogen level medium," issued July 15, 1958); No. 2,938,835 ("Pro-

duction of mutants of the genus Penicillum," issued May 31, 1960); No. 2,986,496 ("Production of antibiotics and antibiotic-containing products," issued May 30, 1961); and No. 3,008,876 ("Compositions containing griseofulvin," issued November 14, 1961).

3. The defendant Imperial Chemical Industries Limited is a corporation organized and existing under the laws of Great Britain, with its principal place of business at Imperial Chemical House, Millbank, London, S.W.1, England. Imperial had a net income of approximately $140 million in 1965 and total assets of approximately $4.2 billion, as of December 31, 1966.

4. Imperial is the owner of United States Patent No. 2,900,304 ("Griseofulvin uses and compositions," issued August 18, 1959) (hereafter referred to as "the Imperial patent").

II. Jurisdiction and Venue

5. Glaxo and Imperial do not reside in the United States. Neither defendant has designated in the United States Patent Office any person on whom may be served process or notice of proceedings affecting the Glaxo or Imperial patents or rights thereunder. This is a proceeding affecting such patents and rights thereunder.

6. Pursuant to 35 U.S.C. § 293 the United States District Court for the District of Columbia has jurisdiction to take any action respecting such patents and rights thereunder, in the same manner as if Glaxo and Imperial were personally within the jurisdiction of such court.

III. The Licensees

7. Johnson & Johnson, Inc. (hereafter referred to as "Johnson") is a corporation organized and existing under the laws of New Jersey, with its principal place of business at 501 George Street, New Brunswick, New Jersey 08903. In 1966 Johnson had net sales of approximately $500 million and total assets of approximately $325 million, as of December 31, 1966.

8. Schering Corporation (hereafter referred to as "Schering") is a corporation organized and existing under the laws of New Jersey, with its principal place of business at 60 Orange Street, Bloomfield, New Jersey. In 1966

Schering had net sales of approximately $130 million and total assets of approximately $125 million, as of December 31, 1966.

9. American Home Products Corporation (hereafter referred to as "American") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 685 Third Avenue, New York, New York 10017. In 1966 American had net sales of approximately $900 million and total assets of approximately $560 million, as of December 31, 1966. American owns and controls Ayerst Laboratories, Inc. (hereafter referred to as "Ayerst"), a corporation organized and existing under the laws of the State of New York.

10. Johnson, Schering, and American (referred to hereafter at times as "the licensees"), are licensed by the defendants under the Glaxo and Imperial patents, and are the only such licensees.

IV. Definitions

11. As used in this complaint:

(a) "Griseofulvin" is the generic name for, and means, the antibiotic compound with the formula 7-chloro-2′,4,6-trimethoxy-6′-methylspiro [benezofuran-2 (3-H), 1′-[2]-cyclohexane]-3, 4′-dione (empirical formula, C_{17} H_{17} Cl O_6);

(b) "Dosage form" means capsules, tablets, and other forms of packaging pharmaceutical products for administration to or use by the ultimate consumer;

(c) "Bulk form" means the form in which pharmaceutical products are manufactured prior to their being packaged into dosage form.

V. Nature of Trade and Commerce

12. Griseofulvin is an antibiotic, antifungal agent administered orally to humans and animals for treatment of external fungus infections such as tinea corporis, tinea cruris, tinea capitis, tinea barbae, tinea urguium and tinea pedis. Griseofulvin is the only effective drug for combating certain fungus infections.

13. Each of the licensees buys griseofulvin in bulk form from one of the defendants (Johnson and Schering from Glaxo, and American from Imperial), which exports it to such licensee, from Great Britain to the United States.

Each licensee mixes such bulk-form griseofulvin with inert ingredients, packages or formulates such mixture into tablets or capsule form, and then sells such griseofulvin, in dosage form only, to purchasers located across state lines from the point at which such packaging or formulation takes place.

14. In 1966 Johnson's sales of such dosage-form griseofulvin products, as tablets sold under the trade names "Grifulvin" and "Grifulvin V," amounted to approximately $1.6 million.

15. In 1966 Schering's sales of such dosage-form griseofulvin products, as tablets sold under the trade names "Fulvicin" and "Fulvicin-U/F," amounted to approximately $3.7 million.

16. In 1966 American's sales of such dosage-form griseofulvin products, as tablets or capsules sold under the trade names "Grisactin" and "Grysio" and under the generic name "griseofulvin," amounted to approximately $1.4 million.

VI. The Patents

17. The product griseofulvin has long been known, and used in the treatment of fungus diseases of plants. The Glaxo and Imperial patents do not claim or purport to claim the product griseofulvin, as such.

18. The Glaxo patents claim methods relating to the manufacture of griseofulvin and certain agricultural-use compositions thereof. The licensees do not practice the Glaxo patents.

19. The Imperial patent claims the method of curing external fungus infections in human beings by internally administering to them "an effective amount" of griseofulvin. The Imperial patent does not teach or disclose, however, what amount constitutes "an effective amount" of griseofulvin for effectuating such cures. In such respect the Imperial patent, contrary to the requirements of 35 U.S.C. § 112, fails to disclose to the public the manner to practice the method in return for which the statutory monopoly was granted; and such method claims are invalid.

20. The Imperial patent claims griseofulvin in tablet form and in certain other dosage forms for oral use. In such respect the Imperial patent, contrary to the require-

ments of 35 U.S.C. §§ 100 and 101, purports to monopolize the old product griseofulvin in the obvious and conventional forms in which it can be taken orally. Such a new use of an old product, however, may be protected under the patent statute only by a method claim; and such product claims in the Imperial patent are invalid.

VII. Violations Charged

21. Beginning at least as early as 1959, and continuing thereafter up to the date of filing of this complaint, the defendants have combined with one another to pool the Glaxo and Imperial patents and to license them in a manner which unreasonably restrains the aforesaid trade and commerce in griseofulvin, in violation of Section 1 of the Sherman Act.

22. Pursuant to such combination, the defendants have entered into and maintained contracts in unreasonable restraint of trade, in the form of licenses, under the Glaxo and Imperial patents, which, as more fully described below, expressly prohibit the licensees from selling unpatented, bulk-form griseofulvin. Unless enjoined by this court the defendants will continue such restraints in effect.

23. On April 1, 1959, Glaxo entered into substantially identical license agreements with Johnson and with Schering, under the Glaxo and Imperial patents. Each agreement grants a license to make, use, and sell griseofulvin. Each agreement expressly provides that the licensee undertakes not to sell griseofulvin in bulk form "to any independent third party without Glaxo's express consent in writing."

24. On December 19, 1962, Imperial entered into an agreement with American, under which Imperial agreed to sell griseofulvin in bulk form to American, and American agreed to resell such griseofulvin only in dosage form. Imperial further granted a license to American under the Glaxo and Imperial patents to effectuate the foregoing arrangement. American expressly agreed not to recall such griseofulvin in bulk form without first securing the consent of Imperial.

25. Pursuant to such agreements, the defendants sell griseofulvin in bulk form to the licensees and the licensees sell griseofulvin only in dosage form to purchasers thereof.

VIII. Effects

26. The effect of the aforesaid contracts has been and is:

(a) to prevent competition between the defendants and the licensees in the sale of griseofulvin in bulk form;

(b) to prevent competition among the licensees in the sale of griseofulvin in bulk form;

(c) to guarantee each licensee freedom from competition from others resulting from the sale of bulk-form griseofulvin by licensees to such others;

(d) to control and restrain the licensees in respect to the manner in which, and the persons through whom, they market griseofulvin;

(e) to prevent access by third persons to sources of griseofulvin in bulk form;

(f) to prevent third persons from packaging bulk-form griseofulvin into dosage form and selling it for use by consumers;

(g) to place restrictions on, or to subject to conditions, the resale of griseofulvin which the licensees purchase from defendants;

(h) to deprive the public, and in particular consumers of drugs, of the benefits of free and open competition in griseofulvin.

Request for Relief

Wherefore, plaintiff requests that the court adjudge:

(1) That the provisions in the licenses from Glaxo to Johnson and Schering, and from Imperial to American, which restrict such licensees from selling griseofulvin in bulk form, are in unreasonable restraint of trade, in violation of Section 1 of the Sherman Act.

(2) That each defendant be permanently enjoined against entering into or maintaining any agreement or understanding with any other persons, in any way limiting the sale of griseofulvin in the United States in bulk form.

(3) That the Imperial patent be declared invalid, or alternatively, that Imperial be ordered to dedicate and disclaim the remaining term of such patent; and that the defendants be ordered not to enforce such patent against any person in any way.

(4) That the defendants be ordered to grant licenses on reasonable terms, and at reasonable, non-discriminatory

royalty rates, to all applicants therefor, on all other United States patents they now own or control, which relate to the manufacture, use, or sale of griseofulvin.

(5) That the plaintiff have such other and further relief as the nature of the case may require and the Court may deem just and proper.

(6) That the plaintiff recover the costs of this suit.

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ANSWER BY IMPERIAL CHEMICAL INDUSTRIES

[Filed Apr. 29, 1968]

[Caption Omitted]

Defendant, Imperial Chemical Industries Limited (referred to hereinafter as "Imperial"), answers the complaint as follows:

First Defense

1. Imperial is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 1 of the complaint.

2. Imperial admits the allegations of paragraph 2 of the complaint, but avers further that Glaxo is the owner of other United States patents relating to griseofulvin and its production under which Imperial is licensed with rights to sub-license.

3. Imperial admits the allegations of the first sentence of paragraph 3 of the complaint. Imperial denies the allegations of the second sentence of the paragraph and avers that Imperial had a net income of approximately $165 million in 1965 and total assets of approximately $2.3 billion, as of December 31, 1966.

4. Imperial admits the allegations of paragraph 4 of the complaint.

5. Imperial admits the allegations of the first two sentences of paragraph 5 of this complaint insofar as they relate to Imperial, but is without knowledge or information sufficient to form a belief with respect to the truth of those allegations as they relate to Glaxo. With respect to the second sentence of paragraph 5, Imperial admits that plaintiff alleges that this is a proceeding affecting such patents and rights thereunder, but avers that this proceeding is not properly brought under 35 U.S.C. Sec. 293 or under any patent or other federal statute.

6. Imperial denies paragraph 6 of the complaint, and refers the Court to the opening sentence of the complaint, which describes this action as one brought pursuant to Section 4 of the Sherman Act (15 U.S.C. Sec. 4) to restrain violations of Section 1 of the Sherman Act (15 U.S.C. Sec. 1).

7. Imperial is without knowledge or sufficient information to form a belief as to the truth of the allegations of paragraph 7 of the complaint.

8. Imperial is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 8 of the complaint.

9. Imperial is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 9 of the complaint.

10. Imperial denies the allegations of paragraph 10 of the complaint, and avers that Johnson and Schering are licensed on a non-exclusive basis by defendant Glaxo under the Glaxo patents and sub-licensed on a non-exclusive basis by defendant Glaxo under the Imperial patent, that American is licensed on a non-exclusive basis by Imperial under the Imperial patent and sub-licensed on a non-exclusive basis by Imperial under the Glaxo patents. Imperial further avers that no other person has requested a license or sub-license from it under the Glaxo and Imperial patents.

11. With respect to paragraph 11 of the complaint:

(a) Imperial denies the allegations of paragraph 11(a) of the complaint, and alleges that the correct formula for "griseofulvin" is 7-chloro-2', 4, 6-trimethoxy-6'-methylspiro [benzofuran-2(3-H), 1'-[2]-cyclohexene]-3, 4'-dione (empirical formula, $C_{17}H_{17}Cl\,O_6$).

(b) Imperial admits that paragraph 11(b) of the complaint defines the term "dosage form" in the manner set forth therein, but avers that, as hereinafter used in this answer, "dosage form" means capsules, tablets and other pharmaceutical products in form suitable for direct internal administration to or use by the patient.

(c) Imperial admits that paragraph 11(c) of the complaint defines the term "bulk form" in the matter set forth therein, but avers that, as hereinafter used in this answer, "bulk form" means the form, of requisite pharmaceutical purity and quality, in which pharmaceutical compounds are available prior to being processed into dosage form.

12. Imperial admits the allegations of the first sentence of paragraph 12 of the complaint, and admits, to the extent it understands, the allegation of the second sentence of the paragraph.

13. Imperial is without knowledge or information sufficient to form a belief as to the truth of the allegations

of paragraph 13 of the complaint insofar as such allegations relate to Johnson, Schering and Glaxo, but admits these allegations insofar as they relate to Imperial and, on information and belief, as to American, and further avers as to American, on information and belief, that American also engages in processing operations such as the fine grinding of griseofulvin.

14. Imperial is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 14 of the complaint.

15. Imperial is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 15 of the complaint.

16. Imperial is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 16 of the complaint.

17. Imperial denies the allegations of the first sentence of paragraph 17 of the complaint. With respect to the allegation of the second sentence of paragraph 17 of the complaint, Imperial points out that the complaint does not define "the product griseofulvin as such" and that it is therefore not able to answer said allegation, but refers to the claims of patents held by Glaxo and Imperial.

18. With respect to the first sentence of paragraph 18, Imperial alleges that the Glaxo patents speak for themselves and refers the Court to the claims thereof. With respect to the second sentence of said paragraph, Imperial is without knowledge or sufficient information to form a belief concerning Schering and Johnson; admits, on knowledge and belief, that American does not practice the Glaxo patents mentioned in the complaint; but avers, on information and belief, that the licensees practice at least one Glaxo patent containing product claims on griseofulvin in bulk and dosage forms.

19. With respect to the first sentence of paragraph 19, Imperial alleges that the Imperial patent speaks for itself and refers the Court to the claims thereof. Imperial denies the other allegations of said paragraph, and further alleges that the plaintiff cannot properly challenge the validity of the Imperial patent in this proceeding.

20. With respect to the first sentence of paragraph 20 of the complaint, Imperial alleges that the Imperial patent speaks for itself and refers the Court to the claims thereof.

Imperial denies the other allegations of said paragraph, and further alleges that the plaintiff cannot properly challenge the validity of the Imperial patent in this proceeding.

21. Imperial denies the allegations of paragraph 21 of the complaint, and avers that Glaxo and Imperial held blocking patents on griseofulvin and that the arrangements between Glaxo and Imperial were necessary to make griseofulvin available to the public.

22. Imperial denies the allegations of paragraph 22 of the complaint.

23. Imperial, on information and belief, admits the allegations of the first two sentences of paragraph 23 of the complaint. Imperial is without knowledge or information sufficient to form a belief as to the allegation of the third sentence of said paragraph.

24. Imperial denies the allegations of paragraph 24 of the complaint, and avers that, by an agreement dated December 19, 1962, Imperial agreed to sell griseofulvin in bulk form to American, and American agreed to resell griseofulvin in dosage form. Further relevant allegations concerning said agreement of December 19, 1962, as amended, appear in paragraphs 28 to 33, inclusive, and paragraph 35 of the answer herein. Imperial further avers that it has granted to American a non-exclusive license under the Imperial patent and non-exclusive sub-licenses under the Glaxo patents.

25. Imperial denies the allegations of paragraph 25 of the complaint.

26. Imperial denies the allegations of paragraph 26 of the complaint.

Second Defense

27. The complaint fails to state a claim against Imperial upon which relief can be granted.

Third Defense

28. On December 19, 1962, Imperial entered into the agreement with American referred to in paragraph 24 of the answer (hereinafter referred to as the "American Distributorship Agreement"), under which Imperial agreed to sell griseofulvin in bulk form to American and American agreed to resell griseofulvin in dosage form.

29. Paragraph 1 of the American Distributorship Agreement provides, in relevant part, that American "will place firm orders with us [Imperial] from time to time for griseofulvin in bulk containers and we [Imperial] shall execute such orders to the best of our ability, subject to our not being prevented for any reason of force majeure, and having regard to your commitments in the United States, to the quantities available from time to time, the requirements of other customers and the productive capacity of our plant."

30. Paragraph 7 of the American Distributorship Agreement provides that American "will not, without first obtaining our [Imperial's] consent, resell or re-deliver in bulk supplies of griseofulvin."

31. To the best of Imperial's information and belief, American does not engage in the business of reselling pharmacutical products in bulk, but sells pharmaceutical products only in dosage form.

32. Several months prior to the filing of the complaint herein, paragraph 7 of the American Distributorship Agreement, which required American to obtain Imperial's consent before selling griseofulvin in bulk, was cancelled by Imperial and American.

33. Contrary to the allegations of paragraphs 21 and 22 of the complaint, the license granted by Imperial to American does not unreasonably restrain the trade and commerce in griseofulvin in violation of Section 1 of the Sherman Act, and in fact in no wise restricts such trade and commerce.

34. By virtue of the facts alleged in paragraph 28 to 33 of this answer, inclusive, this case is moot and plaintiff is not entitled to an adjudication of the matters charged in the complaint or to any relief against Imperial.

Fourth Defense

35. Imperial re-alleges, as part of its fourth defense, the allegations of paragraphs 28 to 34 of this answer, inclusive. In the light of said allegations, the complaint fails to state a claim against Imperial upon which relief can be granted.

Wherefore, defendant Imperial requests that the Court

deny the relief requested by plaintiff and award judgment in favor of the defendants herein.

SIGMUND TIMBERG
Attorney for defendant
Imperial Chemical Industries Limited

Of Counsel:
C. WILLARD HAYES
JOHN W. MALLEY
PAUL N. KOKULIS
LAWRENCE A. HYMO
of Cushman, Darby and Cushman

APRIL 29, 1968

ANSWER OF DEFENDANT GLAXO GROUP LIMITED [Filed May 2, 1968]

[Caption Omitted]

GLAXO GROUP LIMITED answers the complaint herein as follows:

First Defense

1. In answer to the allegations of Paragraph 1 of the complaint this defendant denies that it is a corporation organized and existing under the laws of Great Britain and states that it is a corporation organized and existing under the laws of England, denies that it had total assets of approximately $180,000,000 as of June 30, 1966, and states that the total capital employed in its business at that time was approximately $135,000,000, and denies that prior to December 1961 it was incorporated under the name "Glaxo Laboratories Limited" and states that prior to January 1, 1962, it was incorporated under that name. This defendant admits the remaining allegations of Paragraph 1.

2. This defendant admits the allegations of Paragraph 2 of the complaint.

3. This defendant denies that it has any knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3 of the complaint, except that it admits that Imperial has a place of business at Imperial Chemical House, Millbank, London, S.W. 1, England.

4. This defendant admits on information and belief the allegations of Paragraph 4 of the complaint.

5. In answer to the allegations of Paragraph 5, this defendant admits that it does not reside in the United States and that it has not designated in the United States Patent Office any person on whom may be served process or notice of proceedings; denies that it has knowledge or information sufficient to form a belief as to the truth of the allegation that Imperial does not reside in the United States and has not designated in the United States Patent Office any person on whom may be served process or notice of proceedings; and denies each and every other allegation of Paragraph 5.

6. This defendant denies the allegations of Paragraph 6.

7. This defendant denies that it has any knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 7 of the complaint, except that it admits that Johnson has a place of business at 501 George Street, New Brunswick, New Jersey.

8. This defendant denies that it has any knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 8 of the complaint, except that it admits that Schering has a place of business at 60 Orange Street, Bloomfield, New Jersey.

9. This defendant denies that it has any knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 9 of the complaint.

10. This defendant denies the allegations of Paragraph 10 of the complaint, and by way of further answer states that Johnson and Schering have been granted licenses under the Glaxo patents and sublicenses under the Imperial patent by defendant Glaxo and on information and belief that American has been granted a license under the Imperial patent and a sublicense under the Glaxo patents by defendant Imperial.

11. This defendant admits that the plaintiff in the complaint has given to the terms "griseofulvin", "dosage form" and "bulk form" the meanings stated in Paragraph 11 of the complaint but denies that the definition of "griseofulvin" is complete or accurate or that the definition of "bulk form" is the correct definition of that term as used in the pharmaceutical industry, and states that as used in that industry "bulk form" means a substance having the requisite qualities and properties for formulation into dosage form.

12. This defendant admits the allegations of Paragraph 12 of the complaint.

13. This defendant denies that it has any knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 13 of the complaint, except that it admits that Johnson and Schering buy griseofulvin in bulk form from Glaxo which exports it to Johnson and Schering from Great Britain and that Johnson and Schering each processes and packages or formulates griseofulvin into tablet or capsule form and then sells the tablets or capsules.

14. This defendant denies that it has any knowledge or

information sufficient to form a belief as to the truth of the allegations of Paragraph 14 of the complaint.

15. This defendant denies that it has any knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 15 of the complaint.

16. This defendant denies that it has any knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 16 of the complaint.

17. This defendant admits that griseofulvin in its broadest and most generic sense has long been known and that the Glaxo and Imperial patents do not claim or purport to claim griseofulvin in its broadest and most generic sense, but denies each and every other allegation of Paragraph 17 of the complaint.

18. In answer to the allegations of the first sentence of Paragraph 18 of the complaint, this defendant states that the description of the Glaxo patents is generally accurate but that the Glaxo patents speak for themselves. This defendant admits the remaining allegations of Paragraph 18.

19. In answer to the allegations of the first sentence of Paragraph 19 of the complaint, this defendant states that the description of the Imperial patent is generally accurate but that the Imperial patent speaks for itself. This defendant denies each and every other allegation of Paragraph 19.

20. In answer to the allegations of the first sentence of Paragraph 20 of the complaint, this defendant states that the description of the Imperial patent is generally accurate but that the Imperial patent speaks for itself. This defendant denies each and every other allegation of Paragraph 20.

21. This defendant denies the allegations of Paragraph 21 of the complaint.

22. This defendant denies the allegations of Paragraph 22 of the complaint.

23. This defendant admits the allegations of Paragraph 23 of the complaint except that it denies that the agreements referred to in the paragraph now contain any restriction on the right of the licensees to sell griseofulvin in bulk form.

24. This defendant denies that it has any knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 24 of the complaint.

25. This defendant denies that it has any knowledge or

information sufficient to form a belief as to the truth of the allegations of Paragraph 25 of the complaint.

26. This defendant denies the allegations of Paragraph 26 of the complaint.

SECOND DEFENSE

This Court lacks jurisdiction over the person of this defendant for the reason that the method utilized by plaintiff to seek to serve this defendant with process was insufficient and ineffective to subject this defendant to this Court's jurisdiction.

WHEREFORE, this defendant demands that the complaint against it be dismissed.

HUGH B. COX
HENRY P. SAILER
PAUL F. MCARDLE
Attorneys for Defendant
Glaxo Group Limited

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, PLAINTIFF, v. GLAXO GROUP LIMITED, IMPERIAL CHEMICAL INDUSTRIES LIMITED, JOHNSON & JOHNSON, INC., SCHERING CORPORATION, DEFENDANTS.	Civil No. 558-68

AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF [Motion for leave to file denied by order dated June 4, 1969, 302 F. Supp., 15-16]

The United States of America, plaintiff, brings this civil action against the defendants, pursuant to Section 4 of the Sherman Act (15 U.S.C. § 4), to restrain them from violation of Section 1 of the Sherman Act (15 U.S.C. § 1); and it alleges:

I. THE PATENTEE DEFENDANTS

1. The defendant Glaxo Group Limited (hereafter referred to as "Glaxo") is a corporation organized and existing under the laws of Great Britain, with its principal place of business at Clarges House, 6-12 Clarges Street, London, W.1., England. Glaxo had net sales of approximately $175 million in 1966, and total assets of approximately $180 million, as of June 30, 1966. Prior to December 1961, Glaxo was incorporated under the name "Glaxo Laboratories Limited."

2. Glaxo is the owner of the following United States patents (hereafter referred to as "the Glaxo patents"): No. 2,843,527 ("Production of griseofulvin in low nitrogen level medium," issued July 15, 1958); No. 2,938,835 ("Production of mutants of the genus Penicillum," issued May 31, 1960); No. 2,986,496 ("Production of antibiotics and antibiotic-containing products," issued May 30, 1961); No. 3,008,876 ("Compositions containing griseofulvin," issued November 14, 1961); and No. 3,330,727 ("Griseo-

fulvin with high specific surface area," issued July 11, 1967).

3. The defendant Imperial Chemical Industries Limited is a corporation organized and existing under the laws of Great Britain, with its principal place of business at Imperial Chemical House, Millbank, London, S.W.1, England. Imperial had a net income of approximately $140 million in 1965 and total assets of approximately $4.2 billion, as of December 31, 1966.

4. Imperial is the owner of United States Patent No. 2,900,304 ("Griseofulvin uses and compositions," issued August 18, 1959) (hereafter referred to as "the Imperial patent").

II. Jurisdiction and Venue

5. Glaxo and Imperial do not reside in the United States. Neither defendant has designated in the United States Patent Office any person on whom may be served process or notice of proceedings affecting the Glaxo or Imperial patents or rights thereunder. This is a proceeding affecting such patents and rights thereunder.

6. Pursuant to 35 U.S.C. § 293 the United States District Court for the District of Columbia has jurisdiction to take any action respecting such patents and rights thereunder, in the same manner as if Glaxo and Imperial were personally within the jurisdiction of such court.

III. The Licensees and Licensee Defendants

7. The defendant Johnson & Johnson, Inc. (hereafter referred to as "Johnson") is a corporation organized and existing under the laws of New Jersey, with its principal place of business at 501 George Street, New Brunswick, New Jersey 08903. In 1966 Johnson had net sales of approximately $500 million and total assets of approximately $325 million, as of December 31, 1966.

8. The defendant Schering Corporation (hereafter referred to as "Schering") is a corporation organized and existing under the laws of New Jersey, with its principal place of business at 60 Orange Street, Bloomfield, New Jersey. In 1966 Schering had net sales of approximately $130 million and total assets of approximately $125 million, as of December 31, 1966.

9. American Home Products Corporation (hereafter referred to as "American"), not named a defendant herein, is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 685 Third Avenue, New York, New York 10017. In 1966 American had net sales of approximately $900 million and total assets of approximately $560 million, as of December 31, 1966. American owns and controls Ayerst Laboratories, Inc. (hereafter referred to as "Ayerst"), a corporation organized and existing under the laws of the State of New York.

10. Johnson, Schering, and American (referred to hereafter at times as "the licensees"), are licensed by the patentee defendants under the Glaxo and Imperial patents, and are the only such licensees.

IV. Definitions

11. As used in this complaint:

(a) "Griseofulvin" is the generic name for, and means, the antibiotic compound with the formula 7-chloro-2',4,6-trimethoxy-6'-methylspiro [benzofuron-2 (3-H), 1'-[2]-cyclohexene]-3, 4'-dione (empirical formula, C_{17} H_{17} Cl O_6);

(b) "Dosage form" means capsules, tablets, and other forms of packaging pharmaceutical products for administration to or use by the ultimate consumer;

(c) "Bulk form" means the form in which pharmaceutical products are manufactured prior to their being packaged into dosage form.

V. Nature of Trade and Commerce

12. Griseofulvin is an antibiotic, antifungal agent administered orally to humans and animals for treatment of external fungus infections such as tinea corporis, tinea cruris, tinea capitis, tinea barbae, tinea urguium and tinea pedis. Griseofulvin is the only effective drug for combating certain fungus infections.

13. Each of the licensees buys griseofulvin in bulk form from one of the patentee defendants (Johnson and Schering from Glaxo, and American from Imperial), which exports it to such licensee, from Great Britain to the United States. Each licensee mixes such bulk-form griseofulvin with inert ingredients, packages or formulates such mixture into

tablet or capsule form, and then sells such griseofulvin, in dosage form only, to purchasers located across state lines from the point at which such packaging or formulation takes place.

14. In 1966 Johnson's sales of such dosage-form griseofulvin products, as tablets sold under the trade names "Grifulvin" and "Grifulvin V," amounted to approximately $1.6 million.

15. In 1966 Schering's sales of such dosage-form griseofulvin products, as tablets sold under the trade names "Fulvicin" and "Fulvicin-U/F," amounted to approximately $3.7 million.

16. In 1966 American's sales of such dosage-form griseofulvin products, as tablets or capsules sold under the trade names "Grisactin" and "Grysio" and under the generic name "griseofulvin," amounted to approximately $1.4 million.

VI. The Patents

17. The product griseofulvin has long been known, and used in the treatment of fungus diseases of plants. The Glaxo and Imperial patents do not claim or purport to claim the product griseofulvin, as such.

18. The Imperial patent claims the method of curing external fungus infections in human beings by internally administering to them "an effective amount" of griseofulvin. The Imperial patent does not teach or disclose, however, what amount constitutes "an effective amount" of griseofulvin for effectuating such cures. In such respect the Imperial patent, contrary to the requirements of 35 U.S.C. § 112, fails to disclose to the public the manner to practice the method in return for which the statutory monopoly was granted; and such method claims are invalid.

19. The Imperial patent claims griseofulvin in tablet form and in certain other dosage forms for oral use. In such respect the Imperial patent, contrary to the requirements of 35 U.S.C. §§ 100 and 101, purports to monopolize the old product griseofulvin in the obvious and conventional forms in which it can be taken orally. Such a new use of an old product, however, may be protected under the patent statute only by a method claim; and such product claims in the Imperial patent are invalid.

20. Glaxo patent No. 3,330,727 claims griseofulvin in the

form of particles "having a specific surface area of at least 0.75×10^4 cm.^{2}/g and tablets, capsules, and other pharmaceutical preparations containing such particles; the patent also claims such griseofulvin particles having a specific surface area of at least 0.9×10^4 cm.^{2}/g and at least 1.2×10^4 cm.^{2}/g. Griseofulvin in the form of such particles was known and used by others in this country, and was described and disclosed in printed publications, prior to the alleged invention thereof by the applicant for such patent; and was described and disclosed in printed publications, and was in public use and on sale in this country, more than a year prior to the date of such application. Such patent is invalid by reason of the provisions of 35 U.S.C. §§ 102(a) and 102(b), and for the reasons set forth in paragraph 19 of this complaint.

VII. First Violation Charged

21. Beginning at least as early as 1959, and continuing thereafter up to the date of filing of this complaint, the defendants have combined with one another to pool the Glaxo and Imperial patents and to license them in a manner which unreasonably restrains the aforesaid trade and commerce in griseofulvin, in violation of Section 1 of the Sherman Act.

22. Pursuant to such combination, the defendants have entered into and maintained contracts in unreasonable restraints of trade, in the form of licenses, under the Glaxo and Imperial patents, which, as more fully described below, expressly prohibit the licensees from selling patented or unpatented, bulk-form griseofulvin. Unless enjoined by this court the defendants will continue such restraints in effect.

23. On April 1, 1959, Glaxo entered into substantially identical license agreements with Johnson and with Schering, under the Glaxo and Imperial patents. Each agreement grants a license to make, use, and sell griseofulvin. Each agreement expressly provides that the licensee undertakes not to sell griseofulvin in bulk form "to any independent third party without Glaxo's express consent in writing."

24. On December 19, 1962, Imperial entered into an agreement with American, under which Imperial agreed to sell griseofulvin in bulk form to American, and American agreed to resell such griseofulvin only in dosage form.

Imperial further granted a license to American under the Glaxo and Imperial patents to effectuate the foregoing arrangement. American expressly agreed not to resell such griseofulvin in bulk form without first securing the consent of Imperial.

25. Pursuant to such agreements, the patentee defendants sell griseofulvin in bulk form to the licensees and the licensees sell griseofulvin only in dosage form to purchasers thereof.

VIII. Second Violation Charged

26. Beginning at least as early as 1958, and continuing thereafter up to the present date, the defendant Glaxo, in violation of Section 1 of the Sherman Act, has combined and conspired with its nonexclusive licensees Johnson and Schering to boycott other persons and exclude them from the manufacture and sale of griseofulvin in the United States, in unreasonable restraint of the aforesaid trade and commerce in griseofulvin. Such combination and conspiracy has comprised a continuing agreement, undertaking, and understanding among Glaxo, Johnson, and Schering that Glaxo would not grant a license under the Glaxo patents to Merck & Co. or to others, to make, use, or sell griseofulvin.

VIII. Effects

27. The effect of the aforesaid contracts has been and is:

(a) to prevent competition between the patentee defendants and the licensees in the sale of griseofulvin in bulk form;

(b) to prevent competition among the licensees in the sale of griseofulvin in bulk form;

(c) to guarantee each licensee freedom from competition from others resulting from the sale of bulk-form griseofulvin by licensees to such others;

(d) to control and restrain the licensees in respect to the manner in which, and the persons through whom, they market griseofulvin;

(e) to prevent access by third persons to sources of griseofulvin in bulk form;

(f) to prevent third persons from packaging bulk-form griseofulvin into dosage form and selling it for use by consumers;

(g) to place restrictions on, or to subject to conditions, the resale of griseofulvin which the licensees purchase from the patentee defendants;

(h) to deprive third persons of the opportunity to secure, and to deprive Glaxo of the opportunity to grant, licenses under the Glaxo patents, without the prior approval of Johnson and Schering;

(i) to exclude third persons from the manufacture and sale of griseofulvin without the prior approval of Johnson and Schering;

(j) to deprive the public, and in particular consumers of drugs, of the benefits of free and open competition in griseofulvin.

Request for Relief

Wherefore, plaintiff requests that the court adjudge:

(1) That the provisions in the licenses from Glaxo to Johnson and Schering, and from Imperial to American, which restrict such licensees from selling griseofulvin in bulk form, are in unreasonable restraint of trade, in violation of Section 1 of the Sherman Act.

(2) That each defendant be permanently enjoined against entering into or maintaining any agreement or understanding with any other persons, in any way limiting the sale of griseofulvin or of any other pharmaceutical product in the United States in bulk form.

(3) That the Imperial patent be declared invalid, or alternatively, that Imperial be ordered to dedicate and disclaim the remaining term of such patent; that Glaxo patent No. 3,330,727 be declared invalid, or alternatively that Glaxo be ordered to dedicate and disclaim the remaining term of such patent; and that the defendants be ordered not to enforce such patents against any person in any way.

(4) That the patentee defendants be ordered to grant licenses on reasonable terms, and at reasonable, non-discriminatory royalty rates, to all applicants therefor, on all other United States patents they now own or have the right to license, which relate to the manufacture, use, or sale of griseofulvin; and that they make available to such licensees the know-how relating to griseofulvin manufacture, in the possession or control of defendant.

(5) That each patentee defendant, for a period of eight

years, be required to sell griseofulvin in bulk, on non-discriminatory terms, to each applicant therefor.

(6) That Glaxo, Johnson, and Schering have violated Section 1 of the Sherman Act by combining and conspiring with one another to deny licenses under the Glaxo patents to third parties.

(7) That defendants Glaxo, Johnson, and Schering be enjoined from entering into or maintaining any agreement or understanding with any person, in respect to any United States patent, other than an agreement for a sole and exclusive license under such patent, that any third party or parties will not be licensed under such patent.

(8) That the plaintiff have such other and further relief as the nature of the case may require and the Court may deem just and proper.

(9) That the plaintiff recover the costs of this suit.

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AFFIDAVIT OF JAMES H. WALLACE, Dated Oct. 30, 1968

[Caption Omitted]

* * * * *

2. The attached exhibit GX-1 is a true copy of United States Patent No. 2,900,304, referred to in the complaint and in this motion as the "Imperial Patent."

3. The attached exhibits GX-2—GX-4 are true copies of promotional literature and "package inserts" received by the government from defendants' griseofulvin licensees.

4. The attached exhibit GX-5 is a true copy of an article entitled "Studies in the Biochemistry of Micro-Organisms" which appeared at pp. 240-248 of Vol. 33 of *Journal of Biochemistry* (1939).

5. The attached exhibit GX-6 is a true copy of an article entitled "Uptake of Antibiotic Metabolites of Soil Micro-Organisms by Plants" which appeared at pp. 347-349 of Vol. 167 of *Nature* (March 3, 1951).

6. Griseofulvin was disclosed in printed publications at least as early as 1939, as shown by GX-5. Its use as an antifungal agent in plants was disclosed in printed publications at least as early as 1951, as shown by GX-6.

EXHIBIT 1, ANNEXED TO WALLACE AFFT. OF OCT. 30, 1968—U.S. Pat. No. 2,900,304

UNITED STATES PATENT OFFICE

2,900,304
Patented Aug. 18, 1959

2,900,304

GRISEOFULVIN USES AND COMPOSITIONS

Alfred Ronald Martin, Manchester, England, assignor to Imperial Chemical Industries Limited, London, England, a corporation of Great Britain

No Drawing. Application September 3, 1957
Serial No. 681,472

Claims priority, application Great Britain
September 21, 1956

14. Claims. (Cl. 167—65)

This invention relates to fungicidal compositions and more particularly it relates to fungicidal compositions comprising griseofulvin for the treatment of fungus diseases of man and animals.

Griseofulvin is a known antibiotic and it is known to be useful in the treatment of certain fungus diseases of plants. It has not hitherto been used in the treatment of fungus diseases of man and animals.

Furthermore many important fungus diseases of man and animals are skin diseases, for example ringworm and athlete's foot, and these are commonly treated by topical application of medicaments in the form of ointments and the like. Our co-pending U.S. application Serial No. 681,473, of even date herewith, relates to griseofulvin-containing compositions suitable for such topical application. We have also found however that fungus diseases of man and animals may be treated by oral or parenteral administration of suitable compositions comprising griseo-

fulvin. This is particularly surprising in respect of those fungus diseases which are skin diseases.

According to this invention therefore we provide new compositions suitable for the treatment of fungus diseases of man and animals which comprise griseofulvin as active fungicidal ingredient and pharmaceutical excipients known for the production of formulations suitable for oral or parenteral administration.

The griseofulvin is preferably present in the compositions in such proportion by weight that the proportion by weight of griseofulvin in the formulation to be administered lies between 0.1% and 50%.

Compositions suitable for oral administration are the known pharmaceutical forms for such administration, namely for example tablets, pills, syrups, and aqueous or oily suspensions and the excipients used in the production of these formulations are the excipients well known to the pharmacist's art, as are also the means of formulation.

Suitable compositions may be tablets wherein the griseofulvin is mixed with an inert diluent for example calcium carbonate or lactose in the presence of distintegrating agents for example maize starch and lubricating agents for example magnesium stearate. Aqueous suspensions for oral use may contain griseofulvin in aqueous media in the presence of a suitable non-toxic suspending agent for example sodium carboxymethylcellulose and suitable dispersing agents. Suitable dispersing agents may be for example lecithin or condensation products of ethylene oxide with fatty acids for example polyoxyethylene stearate or with fatty alcohols for example heptadeca-ethyleneoxycetanol or with partial esters derived from the fatty acids and hexitols for example polyoxyethylene sorbitol hexa-oleate, or with partial esters derived from the fatty acids and hexitol anhydrides, for example hexitans derived from sorbitol, for example polyoxyethylene sorbitan mono-oleate. Oily suspensions for oral use may be formulated in a suitable vegetable oil for example arachis oil which may contain suitable sweetening agents and preservatives.

For the treatment of animals especially, by oral admin-

istration, the griseofulvin may first be incorporated into food premixes and the said premixes then used for incorporation into animal foodstuffs. The said food premixes may comprise griseofulvin in admixture with a diluent or carrier for example talc or lactose and/or other suitable non-toxic and orally-acceptable ingredients.

Compositions suitable for parenteral administration are the known pharmaceutical forms for such administration, for example sterile suspensions in aqueous and oily media. The excipients used in these formulations are the excipients well known to the pharmacist's art, as are also the means of formulation.

The sterile aqueous suspensions for parenteral administration may be formulated in the presence of parenterally-acceptable suspending agents and dispersing agents. Suitable suspending agents may be for example sodium carboxymethylcellulose, sodium alginate or polyvinyl pyrrolidone and suitable dispersing agents may be lecithin or the ethylene oxide condensation products described above for use as dispering agents in the preparation of oral aqueous suspensions. Suitable injectable oily preparations may be prepared by dispersing griseofulvin in an oily medium for example a vegetable oil for example arachis oil which is known to be non-toxic and parenterally-acceptable.

The invention is illustrated but not limited by the following examples in which the parts are by weight.

Example 1

500 parts of griseofulvin are mixed with 70 parts of calcium carbonate and 200 parts of a 10% maize starch paste are added. The mixture is dried and is then passed through a 16-mesh screen. 5 parts of magnesium stearate are added and the granules are compressed to give tablets suitable for administration.

Example 2

A mixture of 1.5 parts of polyglyceryl ricinoleate and 0.1 part of sodium carboxymethylcellulose is stirred with 90 parts of distilled water. 10 parts of griseofulvin are then added and the mixture is ball-milled. The stable suspension thus obtained is sterilised and is then suitable for administration by injection.

Example 3

150 parts of griseofulvin in fine powder form are mixed with 500 parts of lactose and 100 parts of maize starch and the mixture is treated with sufficient 10% maize starch paste to give a granular mass. This mixture is passed through a 16-mesh sieve and then dried. 8 parts of magnesium stearate are incorporated in the dried product and the resulting granules are then compressed into tablets suitable for administration.

Example 4

A mixture is formulated from 2 parts of griseofulvin and 98 parts of talc and there is thus obtained a composition suitable for use as a premix for admixture with animal foodstuffs.

Example 5

A mixture is formulated from 5 parts of griseofulvin and 95 parts of lactose and there is thus obtained a composition suitable for use as a premix for admixture with animal foodstuffs.

Example 6

100 parts of griseofulvin in fine powder form is added to a finely ground mixture of 29 parts of icing sugar, 0.6 part of sodium saccharine and 0.05 part of propyl gallate and the mixture is stirred until uniform. The compound powder thus obtained is suspended in 870 parts of arachis oil according to the art, 0.35 part of fruit flavour is added and there is thus obtained an oily dispersion suitable for oral use.

Example 7

A mixture of 10 parts of griseofulvin and 90 parts of arachis oil is ball-milled until substantially all the particles are below 50 microns in diameter. The suspension is then sterilised and is then suitable for administration by injection.

Example 8

142 parts of griseofulvin, 0.5 part of heptadeca-ethyl-

eneoxycetanol and 900 parts of water are ball-milled for one hour. 10 parts of medium viscosity sodium carboxymethylcellulose are then added and ball-milling is continued for a further 4 hours until the bulk or mass of the griseofulvin in suspension is 50-60 microns. There is thus obtained a suspension suitable for dilution for oral use for therapeutic purposes for example as a drench for animals.

Example 9

A solution is prepared by dissolving 1.5 parts of methyl p-hydroxybenzoate, 0.2 part of propyl p-hydroxybenzoate, 2.5 parts of refined soya bean lecithin and 8 parts of polyvinylpyrrolidone in 1000 parts of distilled water. The aqueous vehicle so obtained is sterilised by heating in an autoclave. To the sterile aqueous vehicle so obtained 158 parts of sterile micropulverised griseofulvin are added. The resulting mixture is ball-milled for 15 minutes and there is thus obtained a suspension suitable for parenteral administration for therapeutic purposes.

What I claim is:

1. The process for treating man and animals having an external fungus disease which comprises internally administering to said man and animals an effective amount of griseofulvin.

2. The process for treating man and animals having a fungus skin disease which comprises internally administering to said man and animals and effective amount of griseofulvin.

3. A solid anti-fungal composition in shaped dosage unit form for oral administration which comprises griseofulvin as the active anti-fungal ingredient and a solid, non-toxic, orally-ingestible pharmaceutical carrier, said composition containing at least about 0.1% by weight of griseofulvin.

4. Compositions as claimed in claim 3 wherein the griseofulvin is present in such proportion by weight that the proportion by weight of griseofulvin in the formulation to be administered lies between 0.1% and 50%.

5. A solid anti-fungal composition in shaped dosage unit form for oral administration which comprises griseofulvin as the active anti-fungal ingredient, a solid non-toxic orally-ingestible pharmaceutical carrier, a disintegrating agent

and a lubricating agent, said composition containing at least about 0.1% by weight of griseofulvin.

6. A solid anti-fungal composition in tablet form for oral administration which comprises griseofulvin as the active anti-fungal ingredient; a solid non-toxic orally-ingestible pharmaceutical carrier selected from the group consisting of calcium carbonate and lactose; maize starch as a disintegrating agent and magnesium stearate as a lubricating agent, said composition containing at least about 0.1% by weight of griseofulvin.

7. An anti-fungal composition for internal administration comprising griseofulvin as the active anti-fungal ingredient and a non-toxic, orally-ingestible liquid carrier including both a dispersing agent and a flavoring agent, said composition containing at least about 0.1% by weight of griseofulvin.

8. An anti-fungal composition for internal administration comprising griseofulvin as the active anti-fungal ingredient, suspended in a non-toxic, orally ingestible vegetable oil, said composition containing at least about 0.1% by weight of griseofulvin.

9. The composition of claim 8 wherein said oil is arachis oil, said composition being sterile and pyrogen-free.

10. A composition comprising an animal feed having an effective amount of griseofulvin admixed therein.

11. An anti-fungal composition for use as a premix for admixture with an animal foodstuff, said composition comprising griseofulvin as the active anti-fungal ingredient and a solid, non-toxic, orally-ingestible pharmaceutical carrier selected from the group consisting of talc and lactose, said composition including at least about 0.1% by weight of griseofulvin.

12. A liquid anti-fungal composition for internal administration comprising griseofulvin as the active anti-fungal ingredient, suspended in an aqueous non-toxic, orally-ingestible medium including both a suspending agent selected from the group consisting of sodium alginate, polyvinylpyrrolidone and sodium carboxymethylcellulose, and a dispersing agent selected from the group consisting of lecithin and ethylene oxide condensation products with a member of the group consisting of a fatty acid, a fatty alcohol, a partial ester derived from a fatty acid and a hexitol, and a partial ester derived from a fatty acid and a hexitol anhy-

dride; said composition containing at least about 0.1% by weight of griseofulvin.

13. An injectable anti-fungal composition according to claim 12, same being sterile and pyrogen-free.

14. A sterile, pyrogen-free anti-fungal composition for administration by injection comprising griseofulvin, as the active anti-fungal ingredient, suspended in distilled water containing polyglyceryl ricinoleate and sodium carboxymethyl cellulose, said composition including at least about 0.1% by weight griseofulvin.

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EXHIBIT 2 ANNEXED TO WALLACE AFFIDAVIT OF OCTOBER 30, 1968—McNeil (J&J) Package Insert for GRIFULVIN (Griseofulvin Regular Size)—Copr. 1965

* * * * *

GRIFULVIN (griseofulvin regular size) inhibits the growth of those genera of fungi that commonly cause ringworm infections of the hair, skin, and nails, such as:

Trichophyton rubrum
Trichophyton tonsurans
Trichophyton mentagrophytes
Trichophyton interdigitalis
Trichophyton verrucosum
Trichophyton sulphureum
Trichophyton schoenleini
Microsporum audouini
Microsporum canis
Microsporum gypseum
Epidermophyton floccosum

It is *not* effective in:

Bacterial infections
Candidiasis (Moniliasis)
Histoplasmosis
Actinomycosis
Sporotrichosis
Chromoblastomycosis
Coccidioidomycosis
North American Blastomycosis
Cryptococcosis (Torulosis)
Tinea versicolor
Nocardiosis

* * * * *

DURATION OF TREATMENT

Tinea Capitis: four to six weeks.

Following the daily oral administration of GRIVULVIN (griseofulvin regular size) the infected portion of the hair is gradually replaced by normal hair and, in approximately three weeks, physical removal of the infected portions can be performed. In cases due to ectothrix organisms (e.g. M. audouini, M. canis), the infected hair fluoresces bright

green under a Wood's light and is strikingly different from the noninfected portion that grows out after the start of griseofulvin therapy.

Blank has demonstrated that the degree of growth of new hair can readily be determined by placing a hair plucked from the head of a patient under treatment on an agar plate seeded with a sensitive fungus such as Trichophyton rubrum. The new portion of the hair contains active griseofulvin which produces inhibition of the organism. The old portion if the hair contains no antibiotic and therefore produces no inhibition.

Tinea Corporis: two to four weeks.

GRIFULVIN (griseofulvin regular size) is given daily until the skin appears normal and no pathogenic fungi can be cultured from the lesion. The length of therapy is usually two to four weeks, but in those cases where there is also infection of the nails, therapy must be continued until the nails are free of infection.

Tinea Pedis: Four to eight weeks.

The treatment is similar to that for tinea corporis, except that the thickness of the keratin of the soles of the feet necessitates a longer period of therapy before natural processes achieve complete replacement of the diseased tissues. Although the pathogenic fungi will be eliminated by the daily use of GRIFULVIN (griseofulvin regular size), it is important to recognize that local symptomatic therapy may be indicated. The type of local therapy used will depend on the degree of inflammation present and whether there is a monilial involvement. In general, the more inflammation present, the less vigorous should be the local treatment.

Tinea Unguium (Onychomycosis): Depending on rate of nail growth. Fingernails: at least four months; Toenails: at least six months.

The daily oral use of GRIFULVIN (griseofulvin regular size) will effect the deposition of a fungistatic level of the antibiotic in the infected matrix, thus holding the organisms in check pending removal of the keratinized portion of the nail and its replacement by healthy tissue. Since the fingernails grow slowly, the usual period of therapy is at least four months for complete eradication of the infection and complete healing, while in the case of the toenails even a longer period of treatment may be necessary.

* * * * *

Suggested Adult Dosage

A daily dose of 1 Gm. of GRIFULVIN (griseofulvin regular size) given in divided doses, is adequate for most conditions. In the more severe or extensive infections, up to 2 Gm. a day may be used at the beginning of treatment, reducing the dosage to 1 Gm. when the initial clinical response has been obtained.

Suggested Children's Dosage

A dose of GRIFULVIN (griseofulvin regular size) of approximately 10 mg. per pound of body weight per day is effective in most pediatric patients. On this basis, the following dosage schedule for children will be useful:

Children weighing 30 to 50 pounds
250 mg. to 500 mg. daily.
Children weighing more than 50 pounds:
500 mg. to 1.0 Gm. daily.

Clinical experience with griseofulvin in children with ringworm infections indicates that a single daly dose is effective. Clinical relapse will occur if the medication is not continued until the infecting organism is eradicated.

* * * * *

EXHIBIT 3 ANNEXED TO WALLACE AFFIDAVIT OF OCTOBER 30, 1968—AMHO Brochure on Griseofulvin

* * * * *

Griseofulvin has become a reliable treatment for superficial fungus (ringworm) infections. But, when you're taking griseofulvin, don't become impatient. Even this drug cannot take full effect until infected skin, hair, or nails have been "pushed out" and replaced with the new.

It's also true that results depend upon the type of fungus being treated. Ringworm of smooth, nonhairy skin, for example, may take two to four weeks. Probably three to five weeks are needed for ringworm of the scalp. Ringworm of the nails is most difficult of all. Three to six months for fingernails. At least eight to twelve months for toenails.

Of course, these are all average figures that vary greatly with different individuals. Sometimes less time is needed. Often, treatment may take much longer.

* * * * *

EXHIBIT 4 ANNEXED TO WALLACE AFFIDAVIT OF OCTOBER 30, 1968—McNeil (J&J) Package Insert for GRIFULVIN V (Griseofulvin microsize)—Copr. 1965

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Suggested Adult Dosage

The higher blood levels produced by the microsize form permit reduced dosage in some patients. A divided daily dose of 500 mg. will give a satisfactory response in most patients with *tinea corporis, tinea cruris,* and *tinea capitis.*

For those fungous infections more difficult to eradicate such as *tinea pedis* and *tinea unguium* a divided daily dose of 1.0 Gram is recommended.

Suggested Children's Dosage

Approximately 5 mg. of the microsize form per pound of body weight per day is an effective dose for most children. On this basis the following dosage schedule for children is suggested:

Children weighing 30 to 50 pounds—125 mg. to 250 mg. daily.

Children weighing over 50 pounds—250 mg. to 500 mg. daily.

Clinical experience with griseofulvin in children with ringworm infections indicates that a single daily dose is effective. Clinical relapse will occur if the medication is not continued until the infecting organism is eradicated.

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EXHIBIT 15, ANNEXED TO WALLACE AFFT. OF JUNE 13, 1969—U.S. PAT. NO. 3,330,727

UNITED STATES PATENT OFFICE

3,330,727
Patented July 11, 1967

3,330,727
GRISEOFULVIN WITH HIGH SPECIFIC SURFACE AREA

Kenneth Arthur Lees, Northwood England, assignor to Glaxo Laboratories Limited, Greenford, Middlesex, England, a British company

No Drawing. Continuation of application Ser. No. 103,224, Apr. 17, 1961. This application July 15, 1964, Ser. No. 382,923

6 Claims. (Cl. 167—65)

This application is a continuation of copending application Ser. No. 103,224, filed Apr. 17, 1961, now abandoned.

This invention is concerned with improvements in or relating to the antibiotic griseofulvin.

Griseofulvin has recently found considerable use in the treatment of various human and animal diseases. The substance is generally given by internal administration, particularly by mouth but may also be applied topically.

In the majority of preparations the griseofulvin is present in solid form and, for example, for oral administration, the antibiotic may be incorporated in a tablet, capsule or pill or be given in a suspension in some convenient liquid base.

My researches have shown that the uptake of griseofulvin into the blood stream following oral administration of solid griseofulvin is dependent upon the physical nature of the solid. I have thus found that by reducing the particle size of the solid to smaller dimension than the material hitherto used, the peak blood level following oral administration of a given dose is raised. The effect of raising the extent of uptake into the blood of a given dose of griseofulvin also has the important advantage that a detectable concentration is maintained in the blood for a longer period.

Investigation has thus shown that improved uptake of solid griseofulvin may be secured by preparing griseofulvin in particulate form having a specific surface area of at least 0.75×10^4 cm.^{2}/g.

Preferably also the solid griseofulvin should be in crystalline or micro-crystalline form, as distinct from amorphous form.

The invention accordingly comprises solid griseofulvin in particulate form, preferably in crystalline or micro-crystalline form, having a specific surface area of at least 0.75×10^4 cm.^{2}/g.

Whilst good results are obtained with solid griseofulvin having a specific surface area of at least 0.75×10^4 cm.^{2}/g., even better results are obtained by a further particle size reduction below 0.9×10^4 cm.^{2}/g., and better still below 1.2×10^4 cm.^{2}/g.

A still further improvement in absorption has been noted in some cases by reduction in particle size below 1.5 and in some cases 1.7×10^4 cm.^{2}/g.

The improved form of griseofulvin in accordance with the invention may be formulated for oral administration in any convenient form with the aid of suitable pharmaceutical carriers or excipients. Such preparations may be in solid form, for example, tablets, capsules, pills, dragees or other unitary form, or as powders or granules. For the production of such preparations, conventional carriers or excipients may be used as desired.

Orally administrable preparations may also be formulated in liquid form as suspensions or dispersions in a suitable carrier, which may be of an aqueous or oily nature. Such preparations may include other excipients such as suspending agents e.g. colloids, wetting agents, dispersing agents, sweetening agents or flavouring agents as desired.

The production of griseofulvin in small particle size in accordance with the invention may be achieved in various ways. A method of obtaining such material by direct crystallisation which has been found to be particularly convenient is described in Shaw et al. application Ser. No. 103, 343, filed Apr. 17, 1961. Griseofulvin of small particle size can also be obtained directly by the spray-drying of a solution of griseofulvin in a suitable solvent, e.g. chloroform or acetone, although the material so produced may be of an amorphous nature instead of the desired crystalline or

mgicrocrystalline form. The spray dried material may comprise particles of the desired small particle size admixed with larger particles in which case classification of the particles to give a fraction of the desired size is necessary.

Alternatively, griseofulvin of large particle size obtained, for example, by the milling of griseofulvin produced by conventional techniques may be further size-reduced e.g. by passage through a suitable colloid mill or vibratory mill.

To illustrate the advantages of the improved form of griseofulvin according to the invention, a number of experiments were conducted in human volunteers to determine the average uptake of griseofulvin upon oral administration of tablets containing the antibiotic in different particle sizes.

For these experiments groups of six volunteers were asked to swallow either two or four tablets of the griseofulvin sample under test, each tablet containing 2.50 mg. of antibiotic.

The various forms of griseofulvin were thus tested at two dosages i.e. 0.5 g. and 1 g. Blood samples were taken by veni-puncture at 2, 4, 6, 8 and 26 hours and in some groups 50 hours after dosing, and were assayed in duplicate spectrophotofluorometrically. The results are shown in the following table:

TABLE

Specific Surface Area	Dose, g.	Volunteer	Hours After Administration 2	4	6	8	26	50
0.4×10^4 cm.^{2}/g	0.5	1	0.4	0.7	0.7	0.6	0.1	...
		2	*C	0.5	0.5	0.3	0.2	...
		3	0	0.6	0.6	0.4	0.3	...
		4	*C	0.7	0.7	1.0	0.3	...
		5	0	0	0.3	0.3	0.2	...
		6	0.3	0.5	0.5	0.3	0.3	...
Average			0.18	0.50	0.55	0.48	0.23	...
0.8×10^4 cm.^{2}/g	0.5	7	1.0	1.0	0.6	0.5	0.3	...
		8	0.7	1.2	1.2	1.0	0.5	...
		9	0.5	0.6	0.3	0.3	0	...
		10	1.0	0.8	0.6	0.5	0	...
		11	0.3	0.5	0.5	0.2	0	...
		12	0.7	1.2	1.1	0.8	0.6	...
Average			0.70	0.88	0.71	0.56	0.23	...
0.4×10^4 cm.^{2}/g	1	13	0.7	1.1	1.2	1.3	0.6	...
		14	0.7	0.8	0.6	0.5	0.4	...
		15	1.3	1.3	0.7	0.7	0	...
		16	0.7	1.0	0.7	0.8	0.6	...
		17	0.4	0.5	0.2	0.3	0	...
		18	1.0	1.3	0.8	0.8	0	...
Average			0.80	1.00	0.70	0.73	0.27	...

TABLE—Continued

Specific Surface Area	Dose, g.	Volunteer	Hours After Administration 2	4	6	8	26	50
0.8×10^4 cm.²/g	1	19	0.8	1.5	0.4	1.0	0.3	0
		20	0.5	0.7	0.9	1.2	0.4	0.5
		21	0.3	1.5	1.9	1.8	0.9	0.5
		22	0.4	1.2	1.4	1.7	0.8	0.6
		23	1.8	2.2	2.3	2.1	0.7	0
		24	*0.8	0.5	0.7	0.8	0.8	0.4
Average			0.77	1.27	1.43	1.43	0.65	0.33
1.7×10^4 cm.²/g	0.5	25	0.6	1.1	1.1	1.0	0.4	...
		26	0.6	1.0	1.0	0.7	0.4	...
		27	0.6	0.9	0.9	0.9	0.2	...
		28	0.7	0.9	0.9	0.7	0.2	...
		29	0.3	1.0	0.8	0.8	0.2	...
		30	1.0	1.1	0.8	0.8	0.6	...
Average			0.63	1.00	0.93	0.81	0.33	...
1.1×10^4 cm.²/g	0.5	31	1.1	0.9	0.7	1.0	0.6	...
		32	0.2	0	0	0	0.2	...
		33	0.6	1.0	0.9	0.8	0.4	...
		34	0.4	0.6	0.9	1.1	0.4	...
		35	1.1	0.9	0.7	0.6	0.4	...
		36	0.4	0.5	0.7	0.5	0.4	...
Average			0.63	0.65	0.65	0.67	0.40	...
1.7×10^4 cm.²/g	1	37	1.2	1.5	1.1	1.3	0.8	0.4
		38	1.3	2.1	1.8	2.1	1.8	1.3
		39	0.8	1.2	1.1	1.1	1.0	0.3
		40	1.2	1.6	1.3	1.3	0.6	0.3
		41	0.6	1.4	1.7	2.2	1.2	0.4
		42	0.9	1.2	1.0	1.2	0.7	0.2
Average			1.00	1.50	1.33	1.53	1.02	0.48
1.1×10^4 cm.²/g	1	43	0.9	1.1	1.0	0.8	0.6	0.2
		44	1.9	1.5	1.4	1.0	0.3	0
		45	1.2	1.4	1.3	1.2	0.8	Absent
		46	1.3	1.5	1.2	1.0	0.7	0.2
		47	0.9	2.1	2.1	1.9	0.8	0.3
		48	0.5	0.4	0.4	0.5	0.9	0.3
Average			1.12	1.33	1.23	1.07	0.68	0.20

*C = Contaminated blood sample tube.

I now give by way of example only a description of a method of obtaining small particle size griseofulvin by the use of a vibratory mill.

A quantity of griseofulvin from a normal production batch with an approximate specific surface area of 0.4×10^4 cm.²/g. is mixed with distilled water to produce a 40 percent slurry. The slurry is transferred to a suitable grinding container, consisting e.g., of a polyethylene jar or porcelain pot charged with grinding media to a level just below the surface of the slurry. The grinding media may consist of porcelain or marble balls, cylinders of $\frac{1}{2}$" to 2" diameter prepared from sintered alumina or stainless steel balls or rods. The container holding the griseofulvin slurry and grinding charge is clamped to a vibratory

grinding mill, with controlled amplitude of frequency of vibration allowed to operate for a period of time dependent on the specific surface area of the starting material and the product required. This period can vary from several hours to several days, and during the grinding period it may be necessary to add further small quantities of distilled water to the slurry to reduce viscosity as the particle size of the griseofulvin decreases. Samples are withdrawn from the slurry at intervals, vacuum dried and specific surface area determinations carried out, until the desired particle size is obtained. The slurry is then removed from the grinding mill diluted with distilled water and discharged into a Buchner funnel or porcelain filter fitted with a suitable filter paper. Vacuum is applied to remove the water. Recycling of the filtrate is employed to obtain maximum yield. Alternatively the slurry can be discharged into a suitable centrifuge. The grinding media and container are repeatedly rinsed with distilled water to obtain maximum yield. The wet cake is then removed from the filter or centrifuge and vacuum dried at room temperature to constant weight. The dried griseofulvin is then broken down by passing through a 40 mesh sieve.

Although a conventional rotary ball-mill may be used for wet milling the slurry, a greater charge and reduced grinding time can be obtained by using a vibratory mill with sintered alumina grinding media.

The following examples of suitable oral preparations of small particle size griseofulvin are given by way of illustration only:

In the formulation of the following preparations crystalline griseofulvin having a specific surface area of 1.56×10^4 $cm.^2/g.$ is used, prepared by the process described in application Ser. No. 103,343 aforesaid.

Example 1

Tablets for oral use:	Mg.
Griseofulvin (fine particle size)	250
Starch	47
Magnesium stearate	3

The fine particle size griseofulvin is blended with most of the starch. The remaining starch is used in the form of a 10 percent starch paste as the granulating medium.

The damp granules are passed through a No. 12 mesh sieve, dried under vacuum at a temperature not exceeding 25° C. and passed through a No. 16 mesh sieve. The magnesium stearate is blended with the dried granules which are then compressed at 300 mg. per tablet.

Example 2

Capsules:	Mg.
Griseofulvin (fine particle size)	250

Fill into hard gelatine capsules, size 00.

Example 3

Aqueous suspension for oral use:	Percent, w./v.
Griseofulvin (fine particle size)	5
Sucrose	50
Sodium cyclamate	0.3
Saccharin sodium	0.2
Methyl parahydroxybenzoate	0.15
Lecithin	1.0
Methyl cellulose	1.5
Peppermint oil B.P.	0.05
Water to produce 100.	

Dissolve the preservative in the available water, heated to 90° C. Add the sugar, and disperse the methyl cellulose in the hot solution by slowly sprinkling it onto the surface of the liquid, stirred by vortex action. When the sugar is dissolved, allow the mixture to stand overnight to cool and pass through an homogeniser. Absorb the peppermint oil into the griseofulvin powder and blend in the sweetening agents and lecithin. Make a thick slurry of the powders with some of the homogenised mixture and refine by passing through a colloid mill. Dilute the refined slurry with the remaining vehicle, make up to volume and mix well.

I claim:

1. A product consisting of crystalline griseofulvin in particulate form, said griseofulvin having a specific surface area of at least 0.75×10^4 cm.^{2}/g.

2. Griseofulvin as claimed in claim 1 having a specific surface area of at least 0.9×10^4 cm.^{2}/g.

3. Griseofulvin as claimed in claim 1 having a specific surface area of at least 1.2×10^4 cm.^{2}/g.

4. A pharmaceutical preparation comprising crystalline griseofulvin in the form of particles having a specific surface area of at least 0.75×10^4 cm.^{2}/g. and a pharmaceutical carrier, such preparation being adapted for oral administration.

5. A pharmaceutical tablet comprising crystalline griseofulvin in the form of particles having a specific surface area of at least 0.75×10^4 cm.^{2}/g. and at least one tabletting excipient.

6. A pharmaceutical capsule containing crystalline griseofulvin in the form of particles having a specific surface area of at least 0.75×10^4 cm.^{2}/g.

References Cited

FOREIGN PATENTS

795,039 5/1958 Great Britain.

OTHER REFERENCES

Aytoun: American Perfumer and Aromatics, vol. 74, pages 26-28.

Lyman et al.: American Pharmacy (Fourth Edition, 1955), pages 87 and 98.

MacMillan: J. Chem. Soc., London (1952), page 3955.

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Remington: Practice of Pharmacy (Third Edition) (1895), page 179.

HENRY R. JILES, *Primary Examiner.*

NICHOLAS RIZZO, *Examiner.*

ALEX MAZEL, *Assistant Examiner.*

DEFENDANT ICI'S ANSWERS TO INTERROGATORIES PROPOUNDED BY PLAINTIFF JULY 16, 1968

[ANSWERED BY ICI, SEPT. 16, 1968]

Interrogatory No. 1:

List every disease for which Defendant contends Griseofulvin has therapeutic effects. (In answering this interrogatory Defendant may omit listing such diseases as to which it contends that Griseofulvin does not have a substantial such effect.)

Answer:

We do not know whether the matter inquired about is at issue and therefore have no "contentions" at this time with respect to it. According to labeling approved by the Food & Drug Administration, Griseofulvin has therapeutic effects for—

tinea corporis
tinea pedis
tinea cruris
tinea barbae
tinea capitis
tinea unguium
(onychomycosis)

Interrogatory No. 15:

(a) Describe each step in the manufacturing processes used by Defendant, or which Defendant knows that others use, in order to convert Bulk Form Griseofulvin into Finished Pharmaceutical Form products; and

(b) State each way in which each such step significantly differs from the steps involved in the conversion of other Bulk Form drugs into Finished Pharmaceutical Form.

Answer:

(a) Defendant Imperial Chemical Industries manufactures more than one Finished Pharmaceutical Form of

Griseofulvin, including several types of tablets and a suspension. In the case of tablets the steps used are from among the following:

1. The active substance is mixed with excipients.
2. A mixture of active substance and excipients is moistened and passed through a screen. Ribbons which emerge are beaten into moist granules, which are dried with hot air.
3. Dried granules are passed through a sieve.
4. Dried granules are mixed with additional excipient.
5. Dried granules are compressed into tablets.
6. Tablets are spray coated with a solution of coating composition and the coated tablets are air dried.
7. Tablets are put into containers.

In the case of the suspension, the following steps are included:

1. Excipients are dissolved and suspended in water to form a mixture which is chilled.
2. Active substance is dispersed gradually in the liquid with continuous mixing.
3. The mixture of active substance, water and excipients is passed through a colloid mill.
4. The milled mixture is homogenized with addition of more water and excipients.
5. The mixture is filled into bottles.

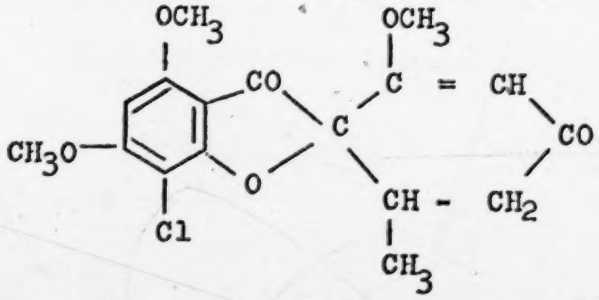
(b) The mixing conditions and times, selection and proportions of excipients and water, drying temperature and times, tablet compression conditions, granulation conditions, granule sizes, and the like are specifically selected to produce products which are appropriately utilized biologically and withstand ordinary handling and storage requirements. These parameters are specific to the active substance and finished pharmaceutical form in each case and specifically differ from parameters selected for other active substances. It would only be possible to itemize differences when a comparison is made with another specific finished pharmaceutical product, but it would be impossible for defendant ICI to make comparison with all such products. Therefore, ICI is unable to provide further answer to this interrogatory.

Interrogatory No. 36:

State the formula for Griseofulvin.

Answer:

The structural formula for Griseofulvin is



Its empirical formula is $C_{17}H_{17}ClO_6$ and its chemical name is 7-chloro-2′, 4, 6-trimethoxy-6′-methylspiro [benzofuran-2(3-H), 1′-[2]-cyclohexene]-3, 4′-dione.

Interrogatory No. 40:

State the amount, by weight and total sales price (received by Imperial), of Bulk Form Regular Size Griseofulvin shipped by Imperial to (i) American, (ii) Johnson, and (iii) Schering, separately, for the years 1965, 1966 and 1967.

Answer:

The weight and total sales price (received by Imperial), of Bulk Form Regular Size Griseofulvin shipped by Imperial to (i) American for the years 1965, 1966 and 1967 were:—

	1965	1966	1967
Weight-Kilos	4,856	3,343	3,852
Sales Price—U.S. $	*375,864	225,892	282,668
—£	134,237		

No sales were made by Imperial to either (ii) Johnson or (iii) Schering.

NOTE-1) Figures relate to invoices/credit notes passed through Imperial's books of account during each year.

2) * U.S. $ amount estimated at sterling equivalent x 2.80.

Interrogatory No. 41:

State the amount, by weight and total sales price (received by Imperial), of Bulk Form Microsize Griseofulvin shipped by Imperial to (i) American, (ii) Johnson, and (iii) Schering, separately, for the years 1965, 1966 and 1967.

Answer:

No Bulk Form Microsize Griseofulvin was shipped by Imperial to (i) American, (ii) Johnson, or (iii) Schering for the years 1965, 1966 and 1967.

Interrogatory No. 42 :

(a) State separately the amount of royalties paid under the Griseofulvin Patent License to Defendant by (i) American, (ii) Johnson, and (iii) Schering separately, for each of the years 1965, 1966 and 1967;

(b) State the royalty rate for each such year for each such Licensee; and

(c) State the dollar amount of each such Licensee's Griseofulvin sales in each such year.

Answer:

(a) The amount of royalties paid under the Griseofulvin Patent License to Imperial by American for each of the years 1965, 1966 and 1967 was:—

	1965	1966	1967
U.S. $	53,258	70,749	58,332

No royalties were paid directly to Imperial by either Johnson or Schering, but royalties were paid to Imperial by Glaxo, part of which originated from Johnson and Schering.

(b) The royalty rate for each such year was 5%

(c) Imperial has no information concerning Johnson's and Schering's sales. The dollar amount of American's Griseofulvin sales in each of such years was—

1965	1,065,165
1966	1,414,979
1967	1,166,644

Interrogatory No. 43:

State the selling price of Bulk Form Griseofulvin as sold by (i) Glaxo and (ii) Imperial, for and during each of the years 1965, 1966, and 1967.

Answer:

Imperial's U.S. selling price for Bulk Form Regular Size Griseofulvin for the years 1965 and 1966 was $78.40 per kilo f.o.b. U. K. In 1967, the selling price for Bulk Form Regular Size Griseofulvin, of somewhat coarser grade than had been supplied in the years preceding, was $77.95 per kilo f.o.b. U. K. In addition, special prices have been quoted to enable American to bid on Government contracts, involving maximum credits ranging from $31.52 per kilo to $32.95 per kilo. Imperial does not know Glaxo's selling prices.

Interrogatory No. 49:

State whether Defendant contends that it has cancelled the Bulk Sale Restriction in any Griseofulvin license since June 1, 1967; if so, state the date of any such cancellation and the parties involved.

Answer:

Imperial does not consider the bulk sale restriction attacked by the Government in this proceeding as part of a Griseofulvin license, but as part of the distributorship agreement between it and American. Said bulk sale restriction in the distributorship agreement was cancelled on or about October 23, 1967, when Mr. R. G. Hoare, Chairman of the Pharmaceuticals Division of Imperial, agreed with Charles M. Johnson, President of Ayerst Laboratories Division of American Home Products Corporation, to cancel the bulk sale restriction. A copy of the letter implementing this agreement is attached hereto.

AMERICAN HOME PRODUCTS CORPORATION

October 1, 1967

665 THIRD AVENUE
NEW YORK 17, N.Y.

Imperial Chemical Industries Limited
Pharmaceuticals Division
Alderley House, Alderley Park
Macclesfield, Cheshire

Dear Sirs:

We refer to various letters exchanged between us relating to the distribution by our Company of various ICI products. It has now been agreed that each of the said letters as set forth in the Schedule immediately below shall be amended by deletion of paragraph 7 contained in each relating to the resale of the covered products in bulk.

Unless otherwise elsewhere amended, the said letters shall remain in full force and effect.

If you agree with the terms of this letter, will you please sign and return the attached duplicate.

Schedule

Date	Product
17th September 1959	"Fluothane"
5th November 1959	"Dictycide"
5th November 1959	"Primidone" B. P.
5th November 1959	"Avlosulfon"
5th November 1959	Chlorhexidine and its Salts
17th December 1959	"Kemithal"
17th December 1959	"Paludrine"
17th December 1959	"Trilene"
4th October 1962	Griseofulvin
6th April 1967	"Atromid-S"

Very truly yours,
American Home Products Corporation

[signatures illegible]

This is a copy of the Agreement referred to in paragraph seven in the Affidavit of Reginald George Hoare sworn before me this 16th day of May 1968.

Interrogatory No. 50:

With respect to each alleged cancellation of the Bulk Sale Restriction set forth in response to the foregoing Interrogatory, state:

(i) All considerations passing between Defendant and the Licensee in payment for such cancellation;
(ii) All acts by the Licensee made in reliance of such cancellation;
(iii) Any detriment to the Licensee or benefit to the Licensor resulting from such acts;
(iv) All reasons of Defendant for such cancellation;
(v) The effect of such cancellation; and
(vi) The manner in which the Licensee was informed of such cancellation.

Answer:

(i) No financial consideration passed between Imperial and its distributor American with respect to such cancellation.

(ii) This portion of the interrogatory should be addressed to American, since it refers to "all acts" by American. Imperial, having given American the freedom to make bulk sales independently, is unaware of the extent to which that freedom has been exercised.

(iii) Imperial considered it a benefit to have removed from the distributorship agreement with American a provision the legality of which it had been advised was being questioned.

(iv) The immediate reason of Imperial for cancelling the bulk sale restriction in its distributorship agreement was that Imperial had been asked to do so by American because the Justice Department, in the course of an inquiry directed to American, was questioning the legality of the provision.

(v) The effect of the cancellation of the above bulk sale restriction was to eliminate any restriction on the freedom of American to resell in bulk form Griseofulvin supplied to American by Imperial.

(vi) See answer to Interrogatory 49.

Interrogatory No. 53:

(a) State the date or approximate date on which De-

fendant was first made aware that the Government was investigating (i) the Griseofulvin License between Glaxo and Schering, (ii) the Griseofulvin License between Glaxo and Johnson, and (iii) the Griseofulvin License between Imperial and American; and

(b) State the manner in which such knowledge was communicated to Defendant.

Answer:

Imperial was not aware that the Government had been investigating the Griseofulvin License between Glaxo and Schering, and between Glaxo and Johnson, respectively, until after the Government's complaint was filed on March 4, 1968. Imperial was first made aware that the Government was investigating the Griseofulvin License between it and American through a letter from Mr. Maurice E. Silverstein to Mr. T. W. M. Bland, Division Secretary of Imperial's Pharmaceuticals Division, dated September 7, 1967, and received by Imperial September 11, 1967. No other information concerning the Government's investigation of the Griseofulvin License between Imperial and American reached Imperial prior to the time the Bulk Sale Restriction was cancelled on or about October 23, 1967.

Interrogatory No. 55:

(a) State Defendant's present policy with regard to selecting the persons to whom it will sell Bulk Form Griseofulvin;

(b) State the names of all persons responsible for forming such policy; and

(c) If there is no such policy, state the names of all persons who would be responsible (i) for forming such a policy if one is formed, and (ii) for deciding the course to follow in respect to individual cases.

Answer:

(a) Imperial's present policy is to refer all inquiries it receives from U. S. sources for Bulk Form Griseofulvin to American, its exclusive U. S. distributor for the sale of

Bulk Form Griseofulvin, and not in any way to influence or restrict American's freedom to make such sales.

(b) The person responsible for forming Imperial's policy with regard to the above is Mr. Reginald G. Hoare, the Chairman of Imperial's Pharmaceuticals Division.

(c) Not applicable.

Interrogatory No. 63:

List by number and title all United States Griseofulvin Patents which Defendant (i) owns, (ii) has a right to license, or (iii) is licensed under.

Answer:

(i) U. S. Patent No.	2,900,304	Griseofulvin uses and compositions
(ii) U. S. Patent Nos.	2,843,527	Production of Griseofulvin in low nitrogen level medium
	2,900,304	Griseofulvin uses and compositions
	2,938,835	Production of mutants of the genus penicillium
	2,986,496	Production of antibiotics and antibiotic containing products
	3,008,876	Compositions containing Griseofulvin
	3,038,839	Process for the production of Griseofulvin
	3,069,328	Production of Griseofulvin
	3,069,329	Production of Griseofulvin
	3,095,360	Griseofulvin production
	3,152,150	Production of Griseofulvin
	3,330,727	Griseofulvin with high specific surface area

Imperial's right to license the foregoing patents is, except in unusual circumstances, limited to American.

(iii) Same list as 63(ii), but omitting U. S. Patent No. 2,900,304.

Interrogatory No. 65:

(a) List each person from whom Defendant has a License under Patents, United States or foreign, relating to Griseofulvin;

(b) Identify each such person by name, address, date such License was entered into, and territories licensed;

(c) Identify by number and country the Patents so licensed;

(d) For each such Patent and License state whether the Defendant has an unlimited right to sublicense on unrestricted terms; and

(e) If such right is not unlimited or unrestricted, explain such limits or restrictions.

Answer:

Note: —By stipulation between the parties, this interrogatory has been restricted to United States patents, and accordingly some parts of the interrogatory no longer apply.

(a) Glaxo Laboratories Limited.

(b) The address of Glaxo Laboratories Limited is 891-995 Greenford Road, Greenford, Middlesex, England. The date of the license is April 26, 1960.

(c) The U. S. patents of Glaxo under which Imperial has been licensed have been listed in answer to Interrogatory 63(iii).

(d) & (e) Under the April 26, 1960 Patent License Agreement between Glaxo and Imperial, Imperial has no right, except in unusual circumstances, to manufacture Griseofulvin except in the United Kingdom, or to license others to manufacture Griseofulvin anywhere in the world. Imperial has the right to sublicense its Associates to make, use and sell preparations containing Griseofulvin. American, Imperial's exclusive distributor in the United States, is its sole Associate in the United States, so that Imperial's sublicensing rights are restricted to American.

Interrogatory No. 66:

List each United States Patent owned by Glaxo or Imperial relating to Griseofulvin, practiced by (i) Glaxo, (ii) Imperial, (iii) American, (iv) Johnson, and (v) Schering; specifying the relevant patent number and claim numbers for each such company.

Answer:

Imperial is not engaged in production or sale of Griseofulvin within the United States and therefore does not practice any U. S. patent relating to Griseofulvin. Imperial is not in a position to answer definitively concerning U. S. patents that may be practiced by American, Johnson and Schering, but believes that U. S. Patent No. 2,900,304 (owned by it) and U. S. Patent No. 3,330,727 (owned by Glaxo) are practiced by American, Johnson and Schering.

Interrogatory No. 67:

(a) State the name and address of each person believed by Defendant to have expressed an interest in purchasing, inquired as to availability of, or requested Bulk Form Griseofulvin from Glaxo, Imperial, American, Johnson, and/or Schering; and
(b) State the date on which and manner in which each such expression of interest, inquiry, or request occurred.

Answer:

Name and Address	Date	Manner
Wayside Gardens, Inc. Mentor, Ohio	March, 1960	Inquiry to American
Washington State University Puyallup, Wash.	September, 1960	Personal inquiry to employee of Imperial
International Chemical Corporation New York, N. Y.	January, 1963	Letter to Imperial
U. S. Summit Corporation 120 Wall Street New York, 5, N. Y.	July, 1963	Inquiry to American
McKesson and Robbins U. S. A.	September, 1963	Telephone inquiry to American

Name and Address	Date	Manner
Unimed, Inc. Morristown, N. J.	May, 1964	Inquiry to Imperial Chemical Industries (New York) Limited
Philipp Bauer Co., Inc. 17 East 45th St. New York 17, N. Y.	November, 1964	Telephone inquiry to Imperial Chemical Industries (New York) Limited
American Cyanamid Co. Lederle Laboratories Division Pearl River, N. Y.	May, 1965	Inquiry to Glaxo Group Limited
Nurani Farma Miami, Fla.	May, 1965	Inquiry to Imperial per Glaxo Group Limited
Pitman, Moore & Co. U. S. A.	November, 1965	Inquiry to Glaxo Group Limited
Allergan Pharmaceuticals 1000 South Grand Avenue Santa Ana, Calif.	February, 1968	Letter to Imperial
Mead, Johnson & Co.	Late 1955	Inquiry to Imperial
Chipman Chemical Co.	November, 1958	Inquiry to Imperial

Interrogatory No. 69:

Identify by patent number and claim number, the patent claims, if any, which Defendant contends are "blocking" and which Glaxo and Imperial placed in the Griseofulvin Patent Pool.

Answer:

Either Glaxo or ICI owns the following British patents pertaining to manufacture of Griseofulvin and/or human and animal thereapeutic formulations containing Griseofulvin:

U. K. Patents
No. 784618
No. 788118
No. 795039
No. 791603
No. 810378
No. 810377
No. 899667
No. 899668

U. K. Applications
7197/59
11097/59
11095/59

and the U. S. corresponding patents listed in the Answer to Interrogatory 63(ii). All of the claims of these patents have blocking effects of the kind indicated in the Answer to Interrogatory 70.

Interrogatory No. 70:

State Defendant's contentions as to whether and why it was necessary to pool Griseofulvin Patents in order to make Griseofulvin available to the public.

Answer:

In replying to this question, objection is taken to plaintiff's inaccurate use of the words "Patent Pool" to cover the contractual arrangement between Glaxo and Imperial whereby each receives rights under the other's Griseofulvin patents (see *Definitions*, I.17). Distinguishing the substance of what Plaintiff is inquiring about from the misleading way in which it has been put in this interrogatory:—

Speaking first to the U. K. market and consumer: In the absence of a contractual arrangement between Imperial and Glaxo whereby Imperial received rights under Glaxo's Bulk Form Griseofulvin ("bulk Griseofulvin") U. K. patents, Imperial could not manufacture the bulk Griseofulvin required to produce Finished Pharmaceutical Form Griseofulvin ("dosage form Griseofulvin"), which it had discovered to have important therapeutic effects. Similarly, unless Glaxo obtained rights under Imperial's U. K. patent for dosage form Griseofulvin for oral administration, Glaxo could not convert its bulk Griseofulvin into dosage form Griseofulvin. Thus, without the contractual arrangement between Imperial and Glaxo, Glaxo would have been blocked from entering the U. K. market for dosage form Griseofulvin and Imperial blocked from entering that market on the basis of its own production of Griseofulvin, and the public correspondingly deprived of the benefits of an important medical discovery. With the conclusion of the

agreement between Imperial and Glaxo, the British public was assured of the benefits accruing from two competing sources of dosage from Griseofulvin.

Coming now to the U.S. market and consumer: Imperial's contractual arrangement with Glaxo, enabling it to manufacture bulk Griseofulvin in the United Kingdom, resulted in its having supplies of bulk Griseofulvin which it could export to the United States for manufacture there into dosage form Griseofulvin and distribution by its U. S. distributor, American. Without the contractual arrangement and Imperial as a source of supply for bulk Griseofulvin, American would have been blocked from entering the U. S. market for dosage form Griseofulvin.

Without obtaining rights under Imperial's U. S. patent on dosage form Griseofulvin, no other U. S. concern could enter the U. S. market for that product. Accordingly, for Glaxo to be able to export bulk Griseofulvin to the United States, it had to assure its U. S. purchasers that they would acquire the rights to use Imperial's U. S. dosage form Griseofulvin patent. Hence, the execution of the contractual agreement between Imperial and Glaxo conferring on Glaxo the right to sublicense its purchasers under Imperial's U. S. patents was necessary to enable Schering and Johnson to enter the U. S. market and make available their production of dosage form Griseofulvin to the public.

Thus, the contractual arrangement between Imperial and Glaxo for the licensing their respective U. K. and U. S. patent rights made available to the American public and pharmaceutical industry two sources of supply of bulk Griseofulvin and three sources of supply of dosage form Griseofulvin.

If Glaxo had not entered the dosage form Griseofulvin market, it would have had no incentive to carry on further research in the Griseofulvin area. Glaxo and its licensees would have been precluded from entering the dosage form Griseofulvin market in all countries of the world where Imperial's invention was patented (including the United Kingdom and United States), unless Glaxo had entered into a contractual arrangement with Imperial enabling it and its licensees to obtain licenses under Imperial's patent. Consequently, the public of the United Kingdom, the United States and other countries would have been deprived of further discoveries made and patented by Glaxo, such as

the valuable discovery that was the subject of Glaxo's Ultrafine Particle Griseofulvin patent.

Interrogatory No. 71:

List all Patents which Imperial has contributed to the Griseofulvin Patent Pool other than United States Patent No. 2,900,304 and corresponding foreign patents.

Answer:

In replying to this question, objection is taken to plaintiff's inaccurate use of the words "patent pool" to cover the contractual arrangement between Glaxo and Imperial whereby either or both receive any rights under any of the other's Griseofulvin patents. This interrogatory has been limited by stipulation to relate to U. S. patents only. There is no other U. S. patent of Imperial which is subject to any contractual arrangement whereby Glaxo receives any rights under Imperial's Griseofulvin patents.

Interrogatory No. 74:

State all reasons why Defendant has not sold Bulk Form Griseofulvin to persons in the United States other than American, Johnson, and Schering.

Answer:

Imperial has no selling organization in the United States for the marketing of pharmaceutical products and has, for many years, been bound by contract with American, whereby American acts as the exclusive distributor within the United States of pharmaceutical products developed by Imperial. The fact that American is Imperial's exclusive distributor necessarily means that Imperial cannot sell Bulk Form Griseofulvin to Johnson, Schering or any other U.S. firm.

Interrogatory No. 75:

List all United States Patents known to Defendant which relate to Griseofulvin.

Answer:

U. S. Patent Nos. 2,843,527
2,900,304

2,938,835
2,986,496
3,008,876
3,029,185
3,038,839
3,069,328
3,069,329
3,090,791
3,095,360
3,147,282
3,152,150
3,160,640
3,325,362
3,330,727

Interrogatory No. 82:

State whether Defendant has entered into any agreement or understanding with any other person in regard to whether or not Defendant will grant additional Licenses under United States Griseofulvin Patents.

Answer:

In the agreement dated April 26, 1960, between Imperial and Glaxo Laboratories for an exchange of licenses under Griseofulvin patents, Imperial undertook not to grant any licenses under its United States Griseofulvin patent, additional to that thereby granted to Glaxo, except to its Subsidiaries and Associates. As already indicated under Interrogatory 65, American, Imperial's exclusive distributor in the United States, is Imperial's sole U. S. Associate.

Interrogatory No. 83:

State whether any Licensee under a United States Griseofulvin License has ever requested Defendant not to, or suggested to Defendant that it should not, grant an additional United States Griseofulvin License to a person at such time not so licensed.

Answer:

No.

Interrogatory No. 84:

State whether Defendant has entered into any agreement or understanding with any other person in regard to whether or not Defendant will sell Bulk Form Griseofulvin to or for persons in the United States other than American, Johnson, and Schering.

Answer:

Because of American's status as the sole importer and distributor of Imperial's Griseofulvin in the United States, Imperial is precluded from supplying Bulk Form Griseofulvin to persons in the United States other than American.

DEFENDANT GLAXO GROUP LIMITED'S ANSWERS TO INTERROGATORIES PROPOUNDED BY PLAINTIFF JULY 16, 1968

[Answered by Glaxo, Oct. 25, 1968; Annexed to Wallace Afft. of Oct. 17, 1969]

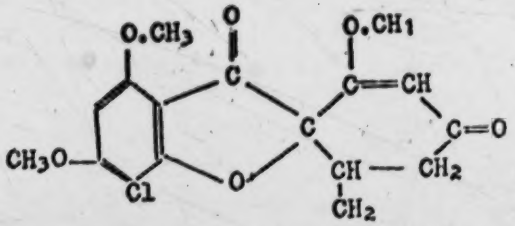
[Caption Omitted]

Interrogatory No. 36:

State the formula for Griseofulvin.

Answer:

An accepted systematic nomenclature based on the trivial name "grisan" is 7-chloro-4,6,2'-trimethoxy-6'-methyl-gris-2'-en-3,4'-dione.



The empirical formula of griseofulvin is $C_{17}H_{17}Cl\ O_6$. The structural formula is

Interrogatory No. 38:

State the amount, by weight and total sales price (received by Glaxo), of Bulk Form Regular Size Griseofulvin shipped by Glaxo to (i) American, (ii) Johnson, and (iii) Schering, separately, for the years 1965, 1966 and 1967.

Answer:

(i)	None			
(ii)	1965	4970	kilograms	$256,151
	1966	1395	"	73,444
	1967	1510	"	90,902
(iii)	1965	3512	kilograms	$211,422
	1966	2260	"	136,052
	1967	3773	"	227,135

NOTE: All years are Glaxo fiscal years beginning on July 1 of year stated. Includes foreign as well as U. S. sales.

Interrogatory No. 39:

State the amount, by weight and total sales price (received by Glaxo), of Bulk Form Microsize Griseofulvin shipped by Glaxo to (i) American, (ii) Johnson, and (iii) Schering, separately, for the years 1965, 1966, and 1967.

Answer:

(i)	None		
(ii)	1965	6550 kilograms	$414,843
	1966	9348 "	521,920
	1967	32477 "	1,628,729
(iii)	1965	10315 kilograms	$620,963
	1966	16994 kilograms	937,976
	1967	16840 kilograms	980,615

NOTE: All years are Glaxo fiscal years beginning on July 1 of year stated. Includes foreign as well as U. S. sales.

Interrogatory No. 42:

(a) State separately the amount of royalties paid under the Griseofulvin Patent License to Defendant by (i) American, (ii) Johnson, and (iii) Schering separately, for each of the years 1965, 1966 and 1967;
(b) State the royalty rate for each such year for each such Licensee; and
(c) State the dollar amount of each such Licensee's Griseofulvin sales in each such year.

Answer:

(a)	(i)	None	
	(ii)	1965	$51,402.31
		1966	58,741.70
		1967	86,041.84
	(iii)	1965	$109,536.94
		1966	114,777.04
		1967	124,630.38
(b)		2½%	

(c)	Johnson & Johnson	1965	$2,132,444.50
		1966	2,439,378.80
		1967	3,528,617.05
	Schering	1965	$4,381,478.00
		1966	4,591,080.00
		1967	4,985,214.00

NOTE: All years are Glaxo fiscal years beginning on July 1 of year stated. Includes foreign as well as domestic sales.

Interrogatory No. 43:

State the selling price of Bulk Form Griseofulvin as sold by (i) Glaxo and (ii) Imperial, for and during each of the years 1965, 1966, and 1967.

NOTE: This interrogatory has been modified by stipulation to refer only to sales made to United States Companies or otherwise known to be destined for sale in the United States.

Answer:

(i) $60.20 per kilo on regular sales; $48.16 per kilo on material used in fulfilling U.S. Government contracts.

(ii) Glaxo is without information sufficient to enable it to respond to this interrogatory.

Interrogatory No. 53:

(a) State the date or approximate date on which Defendant was first made aware that the Government was investigating (i) the Griseofulvin License between Glaxo and Schering, (ii) the Griseofulvin License between Glaxo and Johnson, and (iii) the Griseofulvin License between Imperial and American; and

(b) State the manner in which such knowledge was communicated to Defendant.

Answer:

(a) (i) Orally by Schering personnel in or about January 1968.

(ii) By letter from Johnson dated September 7, 1967.

(iii) On or about March 4, 1968 by a telephone call and from a British newspaper man.

(b)

Interrogatory No. 55:

(a) State Defendant's present policy with regard to selecting the persons to whom it will sell Bulk Form Griseofulvin;

(b) State the names of all persons responsible for forming such policy; and

(c) If there is no such policy, state the names of all persons who would be responsible (i) for forming such a policy if one is formed, and (ii) for deciding the course to follow in respect to individual cases.

Answer:

(a) Glaxo has no policy with regard to selecting the persons to whom it will sell bulk form griseofulvin.

(b) None.

(c) (i) Glaxo has no intention of forming a policy.

(ii) The Board of Directors of Glaxo Group Limited is collectively responsible for deciding the course to follow in individual cases but Mr. A. E. Bide an Executive Member of the Board is the individual functionally responsible for advising the Board on all matters of this nature. He in turn is advised by a large and varying number of members of the Company's staff. The procedure is to consider each request for supplies of bulk form griseofulvin individually and to grant or withhold the License as Glaxo decides in the exercise of its independent judgment to be in the Company's commercial interests at the time.

Interrogatory No. 57:

(a) List all manufacturers of Bulk Form Griseofulvin known to Defendant; and

(b) Give the address of each.

NOTE: This interrogatory has been objected to insofar as it relates to licensees of Glaxo under foreign griseofulvin patents.

Answer:

Glaxo does not know of any manufacturer of bulk griseofulvin in the U.S.A. and does not know the identity of manufacturers elsewhere other than Imperial and Glaxo and its licensees.

Interrogatory No. 63:

List by number and title all United States Griseofulvin Patents which Defendant (i) owns, (ii) has a right to license, or (iii) is licensed under.

Answer:

	U. S. Patent No.	Title
(i)	2,843,527	Production of griseofulvin in low Nitrogen level medium.
	2,938,835	Production of mutants of the genus penicillium.
	3,008,876	Compositions containing griseofulvin.
	2,986,496	Production of antibiotics and antibiotic-containing products.
	3,038,839	Process for the Production of griseofulvin.
	3,152,150	Production of griseofulvin.
	3,095,360	Griseofulvin production.
	3,069,328	Production of Griseofulvin.
	3,069,329	Production of Griseofulvin.
	3,330,727	Griseofulvin with high specific surface area.
(ii)	2,900,304	Griseofulvin uses and compositions.

(iii)	2,900,304	Griseofulvin uses and compositions.
	3,325,362	Isogriseofulvin providing higher griseofulvin blood levels.

Interrogatory No. 64:

(a) List each person licensed by Defendant under Patents, United States or foreign, relating to Griseofulvin;

(b) Identify each such person by name, address, date such License was entered into, and territories licensed;

(c) For each License, identify by number and country the Patents so licensed;

(d) For each such Patent and License state, whether the Licensee has or has not an unlimited right to sublicense on unrestricted terms; and

(e) If such right is not unlimited or unrestricted, describe all limits and/or restrictions.

NOTE: This interrogatory has been modified by stipulation to require only (a) the name and address of each person licensed by Glaxo under United States or foreign griseofulvin patents and (b) a statement as to whether such person can or cannot sell bulk form griseofulvin to or for persons in the United States.

Answer:

(a) Imperial Chemical Industries Limited,
Imperial Chemical House,
Millbank, London, S.W.1. England.

Johnson & Johnson, Inc.
New Brunswick, New Jersey.

Schering Corporation,
Bloomfield, New Jersey.

Lovens Kemiske Fabrik,
Ballerup Byvej,
Ballerup, Denmark.

Nyegaard and Co. A/S.
103 Sandekerven,
Oslo, Norway.

Farbwerke Hoechst A.G.
Frankfurt (M)—Hoechst,
Germany.

Takeda Pharmaceutical Industries Ltd.
27 Doshomachi Nichome Higashiku,
Osaka, Japan.

Laboratories Clin-Comar
20 Rue des Fosses,
St. Jacques,
Paris 5, France.

(b) Imperial, Johnson & Johnson and Schering may sell bulk form griseofulvin in the United States. The others may not.

Interogatory No. 65:

a) List each person from whom Defendant has a License under Patents, United States or foreign, relating to Griseofulvin;
b) Identify each such person by name, address, date such License was entered into, and territories licensed;
c) Identify by number and country the Patents so licensed;
d) For each such Patent and License state whether the Defendant has an unlimited right to sublicense on unrestricted terms; and
e) If such right is not unlimited or unrestricted, explain such limits or restrictions.

NOTE: This interrogatory has been modified to refer only to present or future United States patents.

Answer:

(a) and (b) Imperial Chemical Industries Limited,
Imperial Chemical House,
Millbank, London, S.W.1. England.
License dated April 26th, 1960.
Johnson & Johnson, Inc.
New Brunswick, New Jersey.
License dated April 1, 1959.

(c) U.S.A. Patent 2,900,304 (Imperial)
U.S.A. Patent 3,325,362 (Johnson)
(d) No as to each license.
(e) Right to sublicense subject to consent of Licensor.

Interrogatory No. 66:

List each United States Patent owned by Glaxo or Imperial relating to Griseofulvin, practised by (i) Glaxo, (ii) Imperial, (iii) American, (iv) Johnson, and (v) Schering; specifying the relevant patent number and claim numbers for each such company.

Answer:

Glaxo is without information sufficient to enable it to respond to this interrogatory as to Imperial or American. Certain of the griseofulvin supplied by Glaxo to Johnson and Schering in the United States is the subject of claims Nos. 1, 2 and 3 in U.S. Patent 3,330,727. Glaxo believes that the griseofulvin supplied by it to Johnson and Schering in the United States is formulated into products which are the subject of claims in U.S. Patents 2,900,304 and 3,330,727, but is without knowledge sufficient to specify the particular claims involved.

Interrogatory No. 71:

List all Patents which Imperial has contributed to the Griseofulvin Patent Pool other than United States Patent No. 2,900,304 and corresponding foreign patents.

NOTE: This interrogatory has been modified by stipulation to refer only to United States patents.

Answer:

None.

Interrogatory No. 73:

State all reasons why Defendant has not granted Griseofulvin Patent Licenses to persons in the United States other than American, Johnson, and Schering.

Answer:

Glaxo has not granted any griseofulvin patent license to

American. It has not granted griseofulvin patent licenses to persons in the United States other than Johnson and Schering because Glaxo in the exercise of its independent judgment has not considered it in its best commercial interests to do so. See answer to interrogatory 54 c (ii).

Interrogatory No. 74:

State all reasons why Defendant has not sold Bulk Form Griseofulvin to persons in the United States other than American, Johnson, and Schering.

Answer:

Glaxo has not sold any bulk form griseofulvin to American. It has not sold bulk form griseofulvin to persons in the United States other than Johnson and Schering because Glaxo in the exercise of its independent judgment has not considered it in its best commercial interest to do so. See answer to Interrogatory 55 c (ii).

Interrogatory No. 75:

List all United States Patents known to Defendant which relate to Griseofulvin.

Answer:

The patents listed in response to Interrogatory 63.

Interrogatory No. 83:

State whether any Licensee under a United States Griseofulvin License has ever requested Defendant not to, or suggested to Defendant that it should not, grant an additional United States Griseofulvin License to a person at such time not so licensed.

Answer:

Yes.

Interrogatory No. 84:

State whether Defendant has entered into any agreement or understanding with any other person in regard to whether or not Defendant will sell Bulk Form Griseofulvin

to or for persons in the United States other than American, Johnson, and Schering.

Answer:

No.

Interrogatory No. 85:

State whether any Licensee under a United States Griseofulvin License has ever requested Defendant not to, or suggested to Defendant that it should not sell Bulk Form Griseofulvin to or for a person in the United States other than American, Johnson, and Schering.

Answer:

Glaxo is aware of no request or suggestion made in such terms. It was suggested to it that it should not grant additional griseofulvin licenses in certain fields. Had such licenses been granted they might well have involved the sale of bulk griseofulvin by Glaxo to the Licensee.

AFFIDAVIT OF JAMES H. WALLACE, DATED OCT. 31, 1968

[Caption Omitted]

* * * * * *

2. At least as early as January 14, 1957, E. D. Carry, an official of ICI, proposed to H. W. Palmer, an official of Glaxo, that the two firms should exchange patent rights relating to griseofulvin and enter into other mutual arrangements for the marketing of the product (see GX-1, attached hereto). Also in 1957, representatives of the two firms met and "agreed that we should have patent pool" (GX-2).

3. On April 26, 1960, the defendants ICI and Glaxo formalized their patent pooling agreement (GX-3). Each party undertook to grant patent licenses to the other (GX-3, ¶¶ 2(a), 3(a)). ICI further undertook "not to sell and to use its best endeavors to prevent" its licensees "from selling any griseofulvin in bulk to any Independent Third Party," unless Glaxo gave its "express consent in writing" (GX-3, ¶ 4(e)).

4. Griseofulvin in bulk is the raw material from which griseofulvin pills are made. That is, bulk form griseofulvin is the drug chemical that ICI sells its licensees, in approximately 100-pound drums (50 to 55 kilograms). The bulk product is then mixed with potato starch, corn starch, magnesium stearate, and/or other therapeutically inactive products, and is put into the form of a pill, tablet, or other so-called "dosage form," for sale for ultimate consumption by the patient.

5. On October 4, 1962, ICI sent a proposed letter agreement (GX-4) to American Home Products Corp. ("AMHO"), providing for an exclusive sales agreement on griseofulvin; AMHO agreed to the contract on December 19, 1962. ICI agreed to sell griseofulvin in bulk, and pass title thereon, to AMHO (GX-4, ¶ 1). ICI granted AMHO a license under "any relevant United States patents of ourselves and/or Glaxo . . . to manufacture process, repack and sell *dosage forms* of griseofulvin from griseofulvin supplied to you by us in bulk (GX-4, ¶ 10) (emphasis supplied). The agreement further provided (GX-4):

7) you [AMHO] will not, without first obtaining our [ICI's] consent, resell or re-deliver in bulk supplies of griseofulvin.

See also, to the same effect as the foregoing, ¶¶ 24, 28, 29, and 30 of ICI's Answer to the Complaint.

6. Since such date, ICI has sold substantial amounts of bulk form griseofulvin to AMHO, which it shipped from England to AMHO in the United States. In 1966, such sales were approximately $225,000 (see ICI's answer to plaintiff's July 16, 1968, Interrogatory No. 40).

7. Since such date, AMHO has sold substantial amounts of such griseofulvin, in commerce, only in dosage form; in 1966, such sales by AMHO amounted to approximately $1.4 million (see ICI's answer to plaintiff's July 16, 1968, Interrogatory No. 42(c)).

8. On April 19, 1968, C. M. Johnson, President of Ayerst Laboratories Division of AMHO testified at his deposition (pp. 5-6) as follows:

Q. Does your corporation sell Griseofulvin in any form other than dosage form?
A. The question is do we?
Q. Yes.
A. We have not to date.
Q .Where does your corporation purchase Griseofulvin for processing into dosage form?
A. From the Pharmaceutical Division of ICI, Ltd.
Q. That is Imperial Chemical Industries?
A. Yes Sir.

9. Since such date and up to the date of the filing of this complaint, AMHO and ICI have each declined to sell griseofulvin in bulk to other persons in the United States.

* * * * *

AFFIDAVIT OF JAMES H. WALLACE, DATED JUNE 13, 1969

[Caption Omitted]

• • • • •

2. Background, Formation, and Operation of the Glaxo-ICI Griseofulvin Patent Pool.

a. *Negotiation and Execution of the First Patent Pool Agreement.* At least as early as January 14, 1957, E. D. Carry, an official of defendant Imperial Chemical Industries, Ltd. ("ICI"), proposed to H. W. Palmer, an official of Glaxo that the two firms should exchange patent rights relating to griseofulvin and enter into other mutual arrangements for the marketing of the product (see GX-1, attached to Wallace affidavit attached to plaintiff's October 31, 1968, motion for partial summary judgment against ICI on the restraint on alienation issue, hereafter referred to as the "10-31-68 Wallace affidavit"). Later in 1957, representatives of the two firms met and "agreed that we should have a patent pool" (GX-2, attached to 10-31-68 Wallace affidavit). Glaxo and ICI then entered into a letter agreement dated May 1, 1957 (attached hereto as GX-11). It provides, among other things, for the exchange of licenses under Glaxo's and ICI's respective United Kingdom and corresponding foreign patents relating to griseofulvin.

b. *Glaxo's Negotiations with Prospective United States Licensees and Consultation with ICI Relating Thereto.* Beginning at least as early as March 9, 1956, Glaxo began negotiating with Merck & Co., Inc. ("Merck") respecting a griseofulvin license. See March 9, 1956, letter from Antonie T. Knoppers, Vice President and General Manager of the Merck-Sharp & Dohme International division of Merck, to H. W. Palmer of Glaxo (attached hereto as GX-12). Beginning at least as early as January 2, 1958, Glaxo began negotiating with Johnson & Johnson, Inc. ("J&J") and Schering Corporation ("Schering") respecting licenses under Glaxo's griseofulvin patent rights and the

purchase of bulk form griseofulvin for sale in the United States. See January 2, 1958, letter from A. E. Bide, then Secretary of defendant Glaxo, to J&J (attached hereto as GX-13). Upon the urging of J&J and Schering, Glaxo agreed not to grant a license to Merck (See Wallace affidavit attached to Plaintiff's August 26, 1968, Rule 34 Motion for the production of documents by Glaxo). During these negotiations ICI was consulted about Glaxo's proposed licenses with J&J and Schering (March 5, 1959, letter from N. W. Cusa, Division Techno-Commercial Manager, ICI, to D. N. Lindon, Glaxo, attached hereto as GX-14). Subsequently, Glaxo entered into license agreements on substantially the same terms with J&J and Schering, both dated April 1, 1959. These licenses are described more fully in ¶ 3 of this affidavit.

c. *The Second Pool Agreement.* On April 26, 1960, ICI and Glaxo entered into a second agreement relating to the griseofulvin patent pool (GX-3 of the 10-31-68 Wallace affidavit). This agreement provided for each party to grant to the other licenses under its griseofulvin patent rights (GX-3, ¶¶ (2a) (3a)). ICI further agreed "not to sell and use its best endeavors to prevents its" licensees from selling "any griseofulvin in bulk to any Independent Third Party" unless Glaxo gave its "express consent in writing." (GX-3, ¶ 4(e)).

d. *The Pooled Patents.* Several of Glaxo's United States patents relating to griseofulvin purport to cover processes for the manufacture of griseofulvin, not the product griseofulvin, *per se.* One of the United States patents owned by Glaxo, No. 3,330,727 (attached hereto as GX-15; hereafter referred to as the "727 patent") purports to cover fine particles of griseofulvin (described in the patent as particles griseofulvin having a designated specific surface area) in both bulk form and dosage form. The ICI patent, United States Patent No. 2,900,304 (attached as GX-1 to the Wallace affidavit of 10-30-68 attached to plaintiff's 10-30-68 motion for partial summary judgment that the ICI patent is invalid) purports to cover certain dosage forms of griseofulvin irrespective of particle size, but not to griseofulvin in bulk form. See GX-1 attached to the aforementioned Wallace affidavit of 10-30-68.

e. *Refusals to Grant Griseofulvin Patent Licenses and Refusals to Sell Bulk Form Griseofulvin Except to AMHO, J&J, and Schering.* During the operation of this patent pool third parties have requested griseofulvin patent licenses and the right to purchase bulk form griseofulvin from both ICI and Glaxo. See ICI's answer to plaintiff's interrogatories nos. 67 (attached as GX-5-6 to 10-31-68 Wallace affidavit) and 68 (attached hereto as GX-16-17); Glaxo's answers to plaintiff's interrogatory nos. 67 and 68 (attached hereto as GX-18 and 19, respectively) (inquiry from Burroughs Wellcome & Co.); GX-20 attached hereto (letter request from Rachelle Laboratories, Inc. to Glaxo) and GX-21 attached hereto (letter request from Dooner Laboratories to Glaxo). At least until the filing of the complaint in this case, no such licenses were granted other than those to AMHO, J&J and Schering, which contained bulk sales restrictions. Likewise during the operation of the pool and at least until the filing of the complaint in this case, no bulk sales of griseofulvin in commercial quantities were made by defendants for use or sale in the United States other than from Glaxo to J&J and Schering, and ICI to AMHO.

3. *The Glaxo Licenses with J&J and Schering.*

By agreements dated April 1, 1959, Glaxo licensed J&J (attached hereto as GX-22) and Schering (attached hereto as GX-23) on substantially the same terms. These agreements provide, among other things, that:

a. Glaxo licenses the Glaxo patents and the ICI patents to the United States company in the United States and other specified countries. (GX-22, ¶ 2(b); GX-23, ¶ 2(b));

b. J&J and Schering each undertakes

> "[to] distribute griseofulvin and preparations containing the same solely under its own corporate name or those of its Affiliates."

(GX-22, ¶ 2(c)(i); GX-23, ¶ 2(c)(i));

c. J&J and Schering each undertakes to purchase such griseofulvin as it does not manufacture itself or have manufactured as authorized by the license from Glaxo. (GX-22, ¶ 3(a); GX-23, ¶ 3(a));

d. J&J and Schering each

> "undertakes not to sell or to permit its Affiliates to sell any griseofulvin in bulk to any Independent Third Party without Glaxo's express consent in writing."

(GX-22, ¶ 3(c); GX-23, ¶ 3(c)).

4. *Sales of Griseofulvin to and by the U.S. Licensees*

a. *Glaxo's Sales of Bulk Form Griseofulvin to J&J and Schering.* Pursuant to the aforementioned license agreements between Glaxo and J&J and Glaxo and Schering, Glaxo has sold substantial quantities of bulk form griseofulvin to J&J and Schering in both the unpatented regular size and the fine-particle size, which is purportedly covered by Glaxo's 727 patent, as shown below in Table I for the years 1965 to 1967.

* * * * *

c. *J&J's and Schering's Adherence to the Bulk Sale Provision.* J&J and Schering have each refused to sell commercial quantities of griseofulvin in bulk form despite requests by other drug companies to make such purchase. (*See*, for example, the July 10, 1968, letter from Harry W. McNey, President, McNeil Laboratories, Inc. (J&J's subsidiary that markets griseofulvin) to Eugene C. Dooner, Jr., President, Dooner Laboratories, Inc., attached hereto as GX-27, and the July 3, 1968, letter from Donald R. Longman, Vice President, Domestic Operations, Schering Corporation, to Eugene C. Dooner, Jr., President, Dooner Laboratories, Inc., attached hereto as GX-28.)

5. *The Purported Waivers of the Bulk Sales Provisions.* M. R. Camp, Secretary, Glaxo Group Ltd., wrote J&J a letter dated April 29, 1968, purporting to waive the bulk sales restriction of the Glaxo-J&J griseofulvin license quoted in ¶ 3 d of this affidavit. On April 25, 1968, Irving H. Jurow, General Counsel, Schering, testified at his deposition in this case that he had received a letter from Glaxo on that date purporting to waive the bulk sales restriction of the Glaxo-Schering griseofulvin license. These purported waivers occurred after the plaintiff had completed its precomplaint antitrust investigation which Glaxo

was aware of at least as early as September 7, 1967 (Glaxo's answer to plaintiff's interrogatory no. 53 (attached hereto as GX-29)), filed its complaint, and Glaxo's challenge to service of process was overruled by the Chief Judge of this Court on April 22, 1968.

EXHIBIT 11, ANNEXED TO WALLACE AFFT. OF JUNE 13, 1969—GLAXO-ICI AGREEMENT OF JUNE 21, 1957

1st May, 1957

Imperial Chemical Industries Limited,
Henagan House,
Blackley,
Manchester, 9.

Dear Sirs,

re: *Griseofulvin*

We have found in discussions with you that our two companies have common interests in the investigation of the uses of the antibiotic griseofulvin in the treatment of animal diseases and the commercial exploitation of the results of these investigations to the best interests of our two companies and the public. As it would seem useful to do so, this letter sets out to provide a formal record of the relationship between our two companies on this subject.

I.C.I. is the owner of United Kingdom Provisional Patent Applications Nos. 28904/56 and 28905/56, both of which were filed on 21st September, 1956. Glaxo is the owner of United Kingdom Provisional Patent Applications Nos. 18082/55 (filed 22nd June, 1955) 458/56 (filed 5th January, 1956) and 17554/56 (filed 6th June, 1956).

Glaxo and I.C.I. have agreed to exchange royalty-free non-exclusive rights under all United Kingdom patents issuing on the applications referred to in the preceding paragraph and under all patents equivalent or corresponding to them (including continuations-in-part, patents of addition, reissues, extensions and the like) issuing in countries foreign to the United Kingdom to make use and sell for the prevention or treatment of animal diseases only, compositions containing griseofulvin which are embraced by the description and/or claims contained in any of the patents referred to in this letter. Those rights (unless Glaxo and I.C.I. shall at any time otherwise agree) shall be conveyed for the life of the patents previously referred to or for so long as Glaxo is able and willing to supply to I.C.I. its total requirements of griseofulvin or of material containing griseofulvin whichever is the shorter period.

I.C.I. will purchase its total requirements of griseofulvin or of material containing griseofulvin from Glaxo for so long as Glaxo is able and willing to supply these requirements at a reasonable price. The rights will be sublicensable only to subsidiaries and associates of I.C.I. and Glaxo which I.C.I. and Glaxo effectively control at any time by ownership of a majority of the voting rights or by other means.

If, as we hope, you find the foregoing adequately expresses the arrangements we have discussed, we would be grateful if you would confirm this by signing and dating the enclosed duplicate original copy of this letter in the space provided below and returning the copy to us.

Yours faithfully,
For and on behalf of GLAXO LABORATORIES LIMITED

A. E. Bide signed over 6d. stamp

Company Secretary
A. E. BIDE

Accepted by
IMPERIAL CHEMICAL INDUSTRIES LTD.

(Signed) W. W. Bland

Pharmaceutical Division Secretary

21st June 1957 Date

EXHIBIT 12, ANNEXED TO BOHLING AFFT. OF JULY 7, 1970.

JOHNSON & JOHNSON

New Brunswick, N. J.
November 28, 1958

Subject: "Griseofulvin"—Glaxo Ltd.

Memorandum to File [From W. H. Lycan]

The following is a memorandum of a meeting held on Thursday, November 20, 1958, in the offices of Glaxo Laboratories, Ltd., Greenford, Middlesex, England. The meeting arranged with the help by telephone of Mr. J. F. Brooke was attended in behalf of Glaxo by Mr. H. W. Palmer, Managing Director, Mr. A. E. Bide, Secretary, Dr. Hector Walker, Medical Director, and a Mr. Marsh, Assistant to Mr. Bide. Attending in behalf of John & Johnson were Messrs. H. C. McKenzie and W. H. Lycan. At luncheon, also in attendance was Sir Harry Jeffcott, Chairman of Glaxo, and Dr. McCrea, Director of Chemical Research.

The meeting was opened with a discussion of the reasons for urgency of planning for the possible exploitation of "Griseofulvin" in the American market. It was apparent that Glaxo had not fully understood the situation in the United States and had been caught by surprise by the speed with which Johnson & Johnson had been moving. They readily agreed with the need for urgency, however, when they fully understood the position in which the work of American investigators placed the product in the American market.

At the outset and throughout the meeting, Glaxo made it clear that Johnson & Johnson would be one of those selected for licensing "Griseofulvin" in the United States. Mr. Palmer stated clearly that pending preparation and signing of a formal agreement Glaxo would consider itself morally bound to grant such a license.

The patent situation was discussed in some detail. This has been outlined in previous reports by Drs. Bechtol and Halley and was confirmed by Glaxo. There are presently no American patents issued covering the medical use of

"Griseofulvin." Glaxo does have a process patent issued and, in addition they advise there is a considerable background of know-how which they believe will be important. In addition to the Glaxo patent, I.C.I. has applied for medical use patents in England, the U. S., and numerous other countries. They believe these have a reasonable chance of issuance.

Glaxo and I.C.I. have had discussions with respect to the I.C.I. application and have essentially reached agreement although formal papers have not been signed. Mr. Palmer did state that they have achieved a verbal understanding with the Chairman of I.C.I. and no difficulty is foreseen as far as the American market is concerned. Under this agreement Glaxo will have the right to grant licenses in America. I.C.I. retains the right only for their own subsidiary in the U. S., an organization presently not much larger than an office in New York.

The licensing situation in other countries is not yet as fully clarified since Glaxo and I.C.I. compete in many overseas markets. Mr. Palmer, therefore, wished to wait on further discussions with I.C.I. before discussing possible licenses in markets other than the U. S.

Glaxo then set forth their views on licenses in the U. S. They stated that they were obligated through arrangements between Sir Harry Jeffcott and Mr. Francis Brown of Schering to offer a non-exclusive license to Schering. They had not yet done so, nor had they discussed the matter with Schering. They had the idea that they might want a third licensee and they were a little favorably disposed toward Merck.

Although an effort was made to induce Glaxo to consider exclusive licensing, they were not in a position to accede. They did finally agree that limiting the licenses to two was not unreasonable. Although they did not promise to do so, they promised to seriously consider it.

Glaxo does not believe it feasible to make "Griseofulvin" in England and ship to the U.S. over the long pull. They felt this might divert them from their domestic and regular export markets. There was a discussion of possible manufacturers in the United States, chiefly Merck. Both sides recognized Merck would push for a license to sell as well as make. This was left unresolved because Glaxo felt they were obligated to offer Merck the opportunity to make.

They were not obligated to offer the opportunity to sell, and the implication was that this would be withheld.

It was left that Glaxo would talk with Merck and with Schering and that, following this conversation, agreement would be reached with us concerning relationships with other licensees and for the selection of a supplier in the U. S. In the meantime, and augmenting supplies in the U. S., Glaxo will ship from England or possibly from other producing plants in Australia or elsewhere.

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Johnson & Johnson needs for experimental and clinical amounts of "Griseofulvin" were discussed. Quantities discussed were based on Dr. Hildick-Smith's memorandum to W. H. Lycan under date of November 17. Glaxo agreed to supply 21 K. in the next six months, or more if needed. They will promptly inventory everything in hand and prepare for additional production. First shipments will be made in the next week or ten days. They did make it clear that the interests of Schering or other selected licensee in the United States would have to be considered.

Glaxo agreed that J&J could be identified with the work on "Griseofulvin" from the outset. They will write Dr. Blank advising him of this and authorizing full communication with J&J. They agreed that requests for clinical supplies and information will be referred to Johnson & Johnson. This, of course, was subject to adding a second licensee, if such a licensee is added before publication starts.

It was finally left that Mr. A. E. Bide will prepare a draft of an agreement for J&J as soon as final details with I.C.I. are completed. Glaxo thought this might require a matter of 10 days or two weeks. In the meantime, we were assured of a license and the full cooperation of Glaxo. They will send as complete reports as are presently available and will keep Johnson & Johnson informed in full on their European work.

W. H. Lycan

EXHIBIT 31, ANNEXED TO WALLACE AFFT. OF AUG. 19, 1969

JOHNSON & JOHNSON

New Brunswick, N. J.
November 30, 1958

Subject: "Griseofulvin"—Glaxo Laboratories, Ltd.—Schering

Memorandum to File [from W. H. Lycan]

Following a meeting of the previous evening, Messrs, McKenzie and Lycan met on Saturday, November 29, with Messrs. Francis Brown of Schering, Robert Waterman of Schering, and A. E. Bide of Glaxo.

Mr. Bide stated the position of Glaxo and indicated that he now favors granting only the two licenses, one to Schering and the other to Johnson & Johnson. He restated his position of the previous evening that Glaxo will have to be impartial as between Schering and Johnson & Johnson. He suggested we might find it thus most convenient to work together since neither of us can gain an advantage under the circumstances.

After considerable discussion, we did tentatively agree on a joint program whereunder we would share in laboratory and clinical work. Arrangements were made for a meeting between Schering and Johnson & Johnson personnel next week to set up the program. In the meantime, Glaxo will ship "Griseofulvin" to Johnson & Johnson with the understanding it is to be shared with Schering.

Both Schering and J&J impressed on Mr. Bide that Glaxo cannot expect full pressure on promotion if further licenses are granted. Mr. Bide agreed, subject to approval by his Board at home.

The question of suppliers was discussed in detail. As reported by Mr. Bide, Mr. Brown objected strenuously to Merck. He pointed out that if Sharp & Dohme is not a licensee then Merck will press Glaxo continuously to permit general bulk sales. The position of Penick was reviewed and Schering advised that their experience with Penick on Prednisolone was excellent. Schering has auxiliary extrac-

tion equipment and can help out, in fact, if Penick needs it. They also agreed with J&J that the secondary supplier can be Glaxo itself for the time being and until substantial sales volume is achieved.

The question of advantage was fully discussed. It is apparent that none can be anticipated. It was, therefore, agreed that Dr. Blank should refer to the drug by its generic name, "Griseofulvin," and then when asked about suppliers, he could say both Johnson & Johnson and Schering will have it under their own respective trade names.

It was agreed that we might very well come out at essentially the same time, if and when the drug is to be marketed. In effect, we will produce our N. D. A. application jointly. This may involve talking to F. D. A. and Welch in advance. Details are to be worked out at a meeting with Schering next week.

Mr. Bide agreed to resolve the question of suppliers, particularly Merck, in the United States, as quickly as practical. Meanwhile, Glaxo will rely on Schering and Johnson & Johnson to work out other details here. This includes arrangements for veterinary use. Schering vigorously opposed bringing in a third licensee even though limited to veterinary use. They point out they have ethical veterinary business and proprietary.

On division of supply in the United States, it was agreed that it would be on a 50-50 basis. If one or the other had extra needs or if one or the other had a surplus, the other would be expected to help out if practical but would not be required to do so.

/s/ W. H. Lycan
W. H. Lycan

[Johnson & Johnson Vice President and Director of Research]

EXHIBIT 1, ANNEXED TO BOHLING AFFT. OF JULY 7, 1970.

COPY FOR FILE

[From:]
N. W. Cusa,
Techno-Commercial Department,
[ICI]

[To:]
Mr. E. D. Carey,
Fulshaw Hall,
Wilmslow [ICI].

2nd February, 1959.

GRISEOFULVIN: B.3/7

This is a note to record conversations and arrangements which I have already mentioned to you on the telephone.

Mr. James of Southern Region was approached by a Mr. Heseltine of Squibb's London office with a request that someone from I.C.I. meet Mr. Dahl of Squibb next week to discuss griseofulvin. On your instructions the enquiry was referred to me and I spoke to Mr. James. In the result I have arranged to meet Mr. Dahl on Friday next, 6th February in London for a general discussion, it being understood that I.C.I. is no longer in a position to negotiate regarding griseofulvin in the United States.

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Mr. Bide of Glaxo telephoned on Friday afternoon, 30th January to ask whether I.C.I. had any adverse comment to make on their now more clearly defined proposals for agreement with Schering and Johnson and Johnson.

• • • • •

Mr. Bide was told of the Squibb approach and of the impending meeting and said that he had no arrangements yet to meet Mr. Dahl. He said that he had had some earlier approach from Squibb, along with many other U.S. enquirers, and Squibb had been turned down. It thus appears that the result that someone from this Division meet Mr. Dahl to discuss griseofulvin is an attempt by Squibb to make an arrangement with I.C.I. denied to them by Glaxo. Also possibly it may be expected that Mr. Dahl will not seek further conversation with Glaxo on this occasion.

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N. W. CUSA

EXHIBIT 2, ANNEXED TO BOHLING AFF'T. OF JULY 7, 1970.

COPY FOR FILE

N. W. Cusa,
Techno-Commercial Dept. [ICI]

Mr. E. D. Carey,
Fulshaw Hall,
Wilmslow [ICI].

GRISEOFULVIN: B.3/7

13th February, 1959.

I met Mr. R. Dahl of Squibb in their offices at 17/18, Old Bond Street on Friday, 6th February. The meeting was arranged at Squibb's request because of their alleged interest in griseofulvin.

I explained to Mr. Dahl that I.C.I. was unable to discuss griseofulvin business with Squibb and I explained the reason for this which of course lies in the arrangements which have been made between I.C.I. and Glaxo. Mr. Dahl said that Squibb had already approached Glaxo and had been refused a licence on the ground that Glaxo already had a number of licensees in the U.S. and were not at the present time disposed to add to that number. I gave Mr. Dahl some idea of the patent situation on griseofulvin in such form as will, I hope, have impressed upon him the impossibility of Squibb trading in griseofulvin without a licence from Glaxo under the I.C.I. and Glaxo patents. There is, of course, some danger that Squibb and firms similarly interested may embark on trade in griseofulvin preparations in the absence of granted patents. Mr. Dahl did remark that as recently as six weeks ago a check by Squibb on the patent situation in U.S.A. had revealed no impediment to their operation.

* * * * *

N. W. CUSA.

EXHIBIT 3, ANNEXED TO BOHLING AFF'T. OF JULY 7, 1970.

GLAXO LABORATORIES LTD.
1 CARLOS PLACE
LONDON, W. 1.

24th February 1959.

Francis C. Brown Esq.,
Schering Corporation,
Bloomfield,
New Jersey,
U.S.A.

Dear Mr. Brown,

I am happy now to be able to send you two copies of a draft of our proposed agreement with you on griseofulvin. I am sending an identical draft (save for changes in named companies of course) to Dr. W. H. Lycan today. Your comments will be very welcome, and we would naturally be very glad if you and Johnson & Johnson could present agreed views on the document.

As you will see from the draft, subject in four countries to your not marketing until we have first done so, we have extended your marketing rights to Argentina, Brazil, Canada, Chile, Costa Rica, Formosa, Guatemala, Republic of Honduras, Japan, Mexico, Nicaragua, Panama, Philippines and Uruguay.

The only other point I would just like to mention at this stage is that in Schedule C to the contract we plan to list those of your associated companies which may market griseofulvin, and I would be glad if you would let me have appropriate details for incorporating in the Schedule.

Yours sincerely,
D. N. LINDON.

[handwritten notations illegible]

EXHIBIT 4, ANNEXED TO BOHLING AFF'T. OF JULY 7, 1970.

GLAXO LABORATORIES LTD.
1 CARLOS PLACE
LONDON, W. 1.

24th February 1959.

Dr. W. H. Lycan,
Messrs. Johnson & Johnson,
New Brunswick,
New Jersey,
U.S.A.

Dear Dr. Lycan,

I am happy now to be able to send you two copies of a draft of our proposed agreement with you on griseofulvin. I am sending an identical draft (save for changes in named companies of course) to Mr. Francis Brown today. Your comments will be very welcome, and we would naturally be very glad if you and Schering could present agreed views on the document.

As you will see from the draft, subject in four countries to your not marketing until we have first done so, we have extended your marketing rights to Argentina, Brazil, Canada, Chile, Costa Rica, Formosa, Guatemala, Republic of Honduras, Japan, Mexico, Nicaragua, Panama, Philippines and Uruguay. I have underlined Mexico in the light of your letter to Mr. Bide of February 13th requesting rights in that country. The only other point I would just like to mention at this stage is that in Schedule C to the contract we plan to list those of your associated companies which may market griseofulvin, and I would be glad if you would let me have appropriate details for incorporating in the Schedule.

Yours sincerely,
D. N. LINDON.

EXHIBIT 14, ANNEXED TO WALLACE AFF'T. OF JUNE 13, 1969

IMPERIAL CHEMICAL INDUSTRIES LIMITED
PHARMACEUTICALS DIVISION

ALDERLY PARK
MACCLESFIELD
CHESHIRE

5th March, 1959.

Mr. D. N. Lindon,
Glaxo Laboratories Limited,
1, Carlos Place,
London, W.1.

Dear Mr. Lindon,

GRISEOFULVIN: B.3/7.

Thank you for your letter of 25th February with enclosed copies of the first draft of the Schering and Johnson & Johnson licence agreements. We have now been through these drafts carefully and so far as I can see the only useful comment we can make is on Clause 4(iii). In that clause it is provided that the licensee will pay a royalty of 5% on net sales of all griseofulvin "the whole or any part of the manufacture or subsequent formulation of which is embraced by the claims of any of the Schedule A Patents or Schedule B patents . . . . . ". I think there is restriction here which should be removed. It can be envisaged that the licensee might manufacture griseofulvin without infringing a Glaxo patent and might formulate it without infringing either a Glaxo or an I.C.I. patent, but, if the resultant formulation were used by the customer to treat human or animal fungal disease, either orally or parenterally, there would be infringement of a claim which I.C.I. hopes to get in U.S.A. I suggest that the passage "the whole or any part of the manufacture or subsequent formulation of which" should be replaced by "the manufacture, formulation, sale or use of which".

I shall be glad to know what you think about this.
With kind regards,

YOURS FAITHFULLY,

FOR IMPERIAL CHEMICAL IDUSTRIES LIMITED
PHARMACEUTICALS DIVISION,

N. W. Cusa,

Division Techno-Commercial Manager.

EXHIBIT 5, ANNEXED TO BOHLING AFF'T. OF JULY 7, 1970.

GLAXO LABORATORIES LTD.
1 CARLOS PLACE
LONDON, W. 1.

Mr. Francis Brown,
Vice President,
Schering Corporation,
2, Broad Street,
Bloomfield, N.J.,
U. S. A.

24th March 1959.

Dear Mr. Brown,

Since our recent meetings with Dr. Lycan and Dr. Papa, we have been able to review the general territorial position. As a consequence of this, in addition to the countries I referred to in my letter to you of 24th February 1959, we are now in a position also to offer you rights in the following additional countries:

Bolivia	Paraguay
El Salvador	Peru
Equador	Venezuela

I hope to be writing to you before very long, dealing with the various points raised by Dr. Lycan and Dr. Papa on the draft contract. I am, of course, sending a letter in similar terms to this to Dr. W. H. Lycan of Johnson & Johnson.

Incidentally, I am reminded that I have not had from you the list of your associated companies for incorporation into Schedule C of the proposed contract. I would be grateful if you would let me have this list at your convenience.

With best wishes,

Yours sincerely,
D. N. LINDON

EXHIBIT 6, ANNEXED TO BOHLING AFF'T. OF JULY 7, 1970.

GLAXO LABORATORIES LTD.
1 CARLOS PLACE
LONDON, W. 1.

24th March 1959.

Dr. W. H. Lycan,
Johnson & Johnson,
New Brunswick, N.J.,
U. S. A.

Dear Dr. Lycan,

Since our recent meetings, we have been able to review the general territorial position. As a consequence of this, in addition to the countries I referred to in my letter to you of 24th February 1959, we are now in a position also to offer you rights in the following additional countries:

Bolivia	Paraguay
Equador	Peru
El Salvador	Venezuela

I hope to be writing to you before very long, dealing with the various points you raised on the draft contract. I am, of course, sending a letter in similar terms to this to Mr. Francis Brown of Schering.

Incidentally, I am reminded that I have not had from you the list of your associated companies for incorporation into Schedule C of the proposed contract. I would be grateful if you would let me have this list at your convenience.

With best wishes,

Yours sincerely,
D. N. LINDON

EXHIBIT 7, ANNEXED TO BOHLING AFF'T. OF JULY 7, 1970.

GLAXO LABORATORIES LTD.
1 CARLOS PLACE
LONDON, W. 1.

31st March 1959.

Mr. Francis Brown,
Vice President,
Schering Corporation,
2, Broad Street,
Bloomfield, N.J.,
U. S. A.

Dear Mr. Brown,

In my letter to you of 24th March 1959, referring to six additional countries in which we were offering you rights for griseofulvin, I see I failed to comment on the marketing lead time. You will recall that there are certain territories, referred to in the draft contract you already have, in which we would wish to have a short marketing period ourselves, before you and Johnson & Johnson join in the fun. In the case of the six additional countries now offered to you, we would like to regard Equador, Peru and Venezuela in the same category.

As usual, of course, a letter on similar lines to this is being sent to Dr. W. H. Lycan, of Johnson & Johnson.

Yours sincerely,
D. M. LINDON

EXHIBIT 8, ANNEXED TO BOHLING AFF'T. OF JULY 7, 1970.

GLAXO LABORATORIES LTD.
1 CARLOS PLACE
LONDON, W. 1.

31st March 1959.

Dr. W. H. Lycan,
Johnson & Johnson,
New Brunswick, N.J.,
U. S. A.

Dear Dr. Lycan,

In my letter to you of 24th March 1959, referring to six additional countries in which we were offering you rights for griseofulvin, I see I failed to comment on the marketing lead time. You will recall that there are certain territories, referred to in the draft contract you already have, in which we would wish to have a short marketing period ourselves, before you and Schering join in the fun. In the case of the six additional countries now offered to you, we would like to regard Equador, Peru and Venezuela in the same category.

As usual, of course, a letter on similar lines to this is being sent to Mr. Francis Brown, of Schering.

Yours sincerely,
D. N. LINDON

EXHIBIT 9, ANNEXED TO BOHLING AFF'T. OF JULY 7, 1970.

JOHNSON & JOHNSON

Dear Harry:

During the past few days Mr. Prusak has reviewed the draft of the Glaxo agreement on Griseofulvin with me, with Schering, and with McNeil Laboratories. In general, we believe it reflects faithfully practically everything which we agreed to in our meetings in March. There are a few points on which comment has been made which are recorded below.

1. Definitions, 1(d)—This point was raised by Schering and hardly seems worthy of comment. They expect to clarify it by a letter auxiliary to the agreement. They wish to clarify the fact that in their understanding of the definition of "net sales" that "normal discounts in the trade include cash discounts."

* * * * *

3. *Short Supply*—You will recall that we discussed in Greenford the question of what happens when Griseofulvin is in short supply and orders exceed the availability of the drug. Schering is asking Glaxo to include a provision that, in the event of short supply, they will have equal rights with all of Glaxo's customers. I suspect that this will be handled in Mr. Brown's letter rather than as an added item in the contract.

4. *Improvements, 9(a)*—Schering has raised a rather obscure point with respect to this section. They wish to have an "option" to a license on improvements rather than an automatic license. This would seem to be a legalistic point, but appears to have very little practical significance.

Incidentally, the question of what is an improvement is, as we suspected it would be, rather vaguely written in the agreement. This, you will recall, we discussed at Greenford and we believe that the present language of the agreement reflects as accurately as possible our thoughts at that time. Schering may raise some questions about this, but it seems to me that the agreement, as presently written, is satisfactory.

5. *Trademarks and Get Up, 10*—This is a totally new paragraph which has been inserted and probably arises out of the experience in Canada where they ran into an interference with our Grifulvin trademark . Interpreted literally and in strict legality, the meaning of this section is that, if we select a mark and package design, it is, in effect, subject to approval by Glaxo. I don't see that this is exactly what they intend to do nor that they will be capricious in exercising the right, but this is the right actually granted under this section. Schering appears to be in a little trouble with it since they were slow in registering their Fulvicin trademark in other sections of the World. They may be raising more questions about this section as a result of their delay abroad and they will, no doubt, wish to have exempt from it their Fulvicin mark and other presently existing marks. For our part, we assume that this paragraph does not apply retroactively to the marks that we have already registered.

This would seem to cover all the comments that we have with respect to the agreement and, as far as we are concerned here, you can go ahead and sign in behalf of Johnson & Johnson. I understand that Mr. Lienhard will bring the drafts and this letter with him for completion.

Sincerely yours,
/s/ Bill

W. H. LYCAN/mgd

EXHIBIT 22, ANNEXED TO WALLACE AFF'T. OF JUNE 13, 1969

Agreement Between Johnson and Johnson and Glaxo Laboratories Limited, Dated April 1, 1959

THE AGREEMENT made the 1st day of April One thousand nine hundred and fifty-nine *BETWEEN JOHNSON AND JOHNSON* a Corporation organised and existing under the Laws of the State of New Jersey United States of America and having its principal place of business at New Brunswick New Jersey United States of America (hereinafter referred to as *"J & J"* and *GLAXO LABORATORIES LIMITED* a Company organised and existing under the Laws of England and having its registered office at 891-995 Greenford Road Greenford Middlesex England (hereinafter referred to as *"GLAXO"*) .....

WITNESSETH that *WHEREAS* .....

(A) GLAXO is the owner of the patents and patent applications listed in Schedule A hereto (the said patents and patent applications and any patents granted thereon and any continuations reissues and extensions of any of the same shall hereinafter be referred to as the "Schedule A Patents") all of which relate to the production of griseofulvin and preparations containing the same and is the owner of valuable technical and other confidential information relating thereto not disclosed in the Schedule A Patents (all such information for so long as it shall remain confidential to *GLAXO* and its licencees and sublicencees shall be referred to hereinafter as the "Know-how") .....

(B) IMPERIAL CHEMICAL INDUSTRIES LIMITED (hereinafter referred to as *I.C.I.*) a company organised and existing under the Laws of England and having its registered office at Imperial Chemical House Millbank London England is the owner of the patent applications listed in Schedule B hereto (which patent applications and any patents granted thereon and any continuations reissues and extensions thereof shall hereinafter be referred to as the "Schedule B Patents") relating to griseofulvin preparations and has by arrangement with *GLAXO* authorised and empowered *GLAXO* to grant non-exclusive sublicences thereunder .....

(C) J & J desires to have licences under the Schedule A Patents and sublicences under the Schedule B Patents and to receive and be authorised to use the Know-how to make or have made and use and sell griseofulvin and preparations containing the same and furthermore desires to purchase griseofulvin in bulk from *GLAXO* to use and sell .....

(D) GLAXO is willing to grant such licences and sublicences and to provide and authorise such use of the Know-how and to meet so far as it is able any requests from *J & J* for the supply of griseofulvin in bulk upon the terms and conditions hereinafter set forth .....

NOW THEREFORE IT IS HEREBY AGREED by and between the parties hereto as follows: .....

DEFINITIONS 1.

Wherever the following expressions are used in this agreement they shall have the meaning specified below unless otherwise expressly provided or repugnant to the context .....

(a) "Affiliates" means such companies associated with *J & J* as are listed in Schedule C hereof or may hereafter be listed therein by mutual written agreement .....

(b) "Associated Companies" means those companies all of whose activities shall be controlled by *GLAXO* or *I.C.I.* as the case may be by ownership of the majority of the voting rights or by other means .....

(c) "Independent Third Party" means any person or organisation corporate or un-incorporate other than *J & J* or Affiliates *GLAXO* or its Associated Companies and *I.C.I.* or its Associated Companies .....

(d) "Net Sales" during any calendar quarter means

(i) in the case of griseofulvin sold by *J & J* and/or Affiliates as such or compounded with any material for which no prophylactic therapeutic or nutritional effect is expressly claimed by *J & J* or Affiliates the net proceeds of sales after deducting all normal and customary trade and quantity discounts and allowances granted to customers excise or other sales taxes which *J & J* and/or Affiliates have to pay or absorb on such sales and

(ii) in the case of griseofulvin sold by *J & J* and/or Affiliates compounded with any material for which *J & J* or Affiliates expressly claim a prophylactic therapeutic

or nutritional effect, the value of the total declared amount of the griseofulvin contained therein calculated at the average price per gramme of griseofulvin obtained by dividing Net Sales made in accordance with Clause 1(d)(i) hereof for the quarter in question by the number of grammes of griseofulvin represented by the said Net Sales *PROVIDED ALWAYS* that solely for the purpose of calculating net sales hereunder human medical sales, veterinary medical sales and animal feed sales, shall be treated separately .....

(e) "Force Majeure" means requisition or interference by any Government State or local authority war strikes lock-outs riot or epidemic diseases Act of God or any other circumstances whatsoever whether eiusdem generis to the above causes or not over which *J & J or GLAXO* as the case may be shall have no control

(f) The singular shall include the plural and vice versa

LICENCE GRANT 2.

(a) GLAXO hereby warrants that it is authorised and empowered by I.C.I. to grant non-exclusive sub-licences under the Schedule B Patents

(b) GLAXO hereby undertakes on receipt of a written request from J & J to transmit the Know-how to J & J and GLAXO hereby grants to J & J and Affiliates sub-licences under the Schedule B Patents and licences and rights under the Schedule A Patents and the Know-how to make griseofulvin in the United States of America (subject always to any provisions in respect thereof hereinafter set forth) and to use and sell griseofulvin and to make use and sell preparations containing the same for human and veterinary use (including animal feeding) in Argentina Bolivia Brazil Canada Chile Costa Rica Equador El Salvador Formosa Guatemala Republic of Honduras Japan Mexico Nicaragua Panama Paraguay Peru Phillippines Uruguay United States of America and Venezuela and the territories possessions and dependencies of any of the same at the date hereof provided that (except in circumstances where an Independent Third Party is selling griseofulvin without GLAXO's consent express or implied) J & J and Affiliates shall not sell griseofulvin in Argentina Brazil Canada Equador Mexico Peru Uruguay or Venezuela until ninety days after the date (which GLAXO shall promptly indicate

to J & J in each case) on which GLAXO's subsidiary company or agent in that country shall have made its first commercial sale of griseofulvin. All sublicences licences and rights granted hereunder shall be non-exclusive non-transferable non-divisible and non-sublicensable save that J & J shall be entitled (subject to any provisions in this agreement in respect thereof and subject to GLAXO's express approval in writing which approval shall not be unreasonably withheld)

(i) To have griseofulvin made for it in the United States of America for use and sale by it and Affiliates in accordance with this agreement

(ii) To make or have griseofulvin made for it in any territory the subject of this agreement outside the United States of America for use and sale by it and Affiliates in accordance with this agreement in circumstances where for commercial reasons affecting such a territory such local manufacture of griseofulvin shall be necessary

In the event that GLAXO shall indicate to J & J that the purchase of griseofulvin manufactured by or on behalf of J & J hereunder is desired by GLAXO or I.C.I. or Associated Companies of either of the same for resale J & J undertakes to use its best endeavours to meet such desires

(c) J & J shall under the sublicences licences and rights herein granted

(i) distribute griseofulvin and preparations containing the same solely under its own corporate name or those of its Affiliates

(ii) advise GLAXO within a reasonable time after the execution of this agreement as to the specific trade names marks or designations under which it will render bills covering the sale of griseofulvin and preparations containing the same and keep GLAXO informed of any changes or new trade names marks or designations which it may thereafter make or adapt for griseofulvin and preparations containing the same and in rendering bills therefor invariably use the trade names marks and designations so furnished to *GLAXO*

(iii) give written notice to *GLAXO* at least nine calendar months prior to the date of the first com-

mercial production of griseofulvin by it or on its behalf in any territory the subject of this agreement and acquaint *GLAXO* fully with the intended scale of such production at that date and for at least the twelve calendar months subsequent thereto .....

(iv) give written notice to *GLAXO* at least nine calendar months prior to obtaining for resale by it or Affiliates griseofulvin manufactured by any Independent Third Party authorised directly or indirectly by *GLAXO* so to do

PROVIDED ALWAYS that *J & J* shall not be required to give the notices referred to in paragraphs (iii) and (iv) of this clause 2(c) in the event that *GLAXO* shall not be able fully to meet such reasonable orders for griseofulvin as shall be placed by *J & J* in accordance with the provisions of Clause 3 hereof .....

BULK SUPPLIES 3.

(a) Save for such griseofulvin as *J & J* and Affiliates shall acquire from manufacture by or on behalf of *J & J* or by any Independent Third Party authorised directly or indirectly by *GLAXO* so to do within the territories the subject of this agreement *J & J* shall seek to purchase all the requirements of *J & J* and Affiliates for griseofulvin from *GLAXO* at such reasonable prices as the parties hereto shall agree in respect thereof. At least ninety days prior to the beginning of each calendar quarter *J & J* shall order from *GLAXO* its and Affiliates requirements for each month of such calendar quarter specifying quality delivery dates and quantities desired and *GLAXO* shall indicate within ten days of the receipt of any such order whether and to what extent it shall be able to meet the same. Delivery shall be made by *GLAXO* to such address as *J & J* shall direct but *J & J* shall pay the landing charges and customs duties and shall reimburse *GLAXO* for the cost of insurance on such shipments. If any quantity of griseofulvin supplied by *GLAXO* hereunder is found by *J & J* not to be of the quality specified by *J & J J & J* shall have the right to return it to *GLAXO* at *GLAXO's* expense provided that notice of *J & J's* intention to return it is given by *J & J* to *GLAXO* within thirty days after the date of receipt of such quantity at such address aforesaid and that such

quantity is actually returned to *GLAXO* within thirty days after the giving of such notice. In the event that in lieu of the return of such quantity *J & J* shall elect to reprocess the same *J & J* shall be entitled to reimbursement from *GLAXO* of the reasonable cost of such reprocessing which cost shall not exceed the expense *GLAXO* would have incurred if such quantity had been returned as aforesaid. ....

(b) In order to assist *GLAXO* in its production planning *J & J* agrees to furnish *GLAXO* at least sixty days prior to the beginning of each calendar year of this agreement with a written estimate of its and Affiliates requirements of griseofulvin from *GLAXO* for such calendar year provided always that *J & J* shall incur no liability in the event its and Affiliates actual requirements for any such calendar year shall fail to equal the written estimate therefor nor shall *J & J's* right to order griseofulvin from *GLAXO* hereunder be limited to any such written estimate .....

(c) *J & J* undertakes not to sell or to permit its Affiliates to sell any griseofulvin in bulk to any Independent Third Party without *GLAXO's* express consent in writing .....

ROYALTY 4.

During the life of this agreement *J & J* shall pay to *GLAXO* in the manner provided in Clause 5 hereof .....

(i) a royalty of 2½% (two and a half percentum) on Net Sales of all griseofulvin supplied by or on behalf of *GLAXO*

(ii) a royalty of 2½% (two and a half percentum) on Net Sales of all griseofulvin manufactured by or on behalf of *J & J* or by any Independent Third Party authorised so to do by *GLAXO* in the manufacture of which is used all or any part of the Know-how and/or any confidential information conveyed by *GLAXO* under the provisions of Clause 9 (a) hereof and

(iii) a royalty of 5% (five percentum) on Net Sales of all griseofulvin manufactured by or on behalf of *J & J* or by any Independent Third Party authorised so to do by *GLAXO* the whole or any part of the manufacture formulation use or sale of which is embraced by any of the claims of any of the Schedule A Patents or Schedule B Patents or any patents or patent applications under which J & J shall be given rights under the provisions

of Clause 9 (a) hereof which exist in the territory of such manufacture formulation use or sale. .....

(iv) Upon the request of *J & J GLAXO* and *J & J* will confer with respect to a possible reduction in the royalties reserved hereunder in respect of sales in any country in the event that *J & J* shall demonstrate that the royalties herein reserved are having a detrimental effect on *J & J's* ability competitively to market griseofulvin and preparations containing the same in such country or in the event that by reason of any operations hereunder *J & J* shall find itself liable to pay a royalty to any third party .....

(v) Nothing contained herein shall obligate *J & J* to pay royalty upon transactions between it, Affiliates or any licencees or sublicencees of *GLAXO* or to pay royalty more than once on sales of griseofulvin or preparations containing the same .....

ACCOUNTING 5.

(a) *J & J* shall keep true and particular accounts of all royalties payable under Clause 4 hereof and shall deliver to *GLAXO* written statements thereof on or before the sixtieth day following the end of each calendar quarter (or any part thereof in the first or last calendar quarter) of this agreement indicating the amount of griseofulvin sold in each country and at the same time shall pay to *GLAXO* or to whomsoever *GLAXO* shall otherwise direct in United States currency available in London England the amount due and payable as reported in any given statement. .....

(b) *GLAXO* shall have the right to have a public accountant of its own selection and at its own expense except one to whom *J & J* may have reasonable objection to examine the relevant accounts of *J & J* for a period of not more than two complete accounting years immediately preceding the date of review to determine whether appropriate accounting and payments has been made .....

TERM 6.

This agreement shall unless sooner terminated continue in full force and effect for seventeen years from the date first above written or until the expiration of the last to

expire of the Schedule A Patents and the Schedule B Patents whichever shall be the later .....

KNOW-HOW 7.

(a) *J & J* hereby undertakes to bind all its agents employees and any independent parties under contract to it for any reason whatsoever having access to any of the Know-how or any confidential information conveyed by *GLAXO* under the provisions of Clause 9 (a) hereof to hold the same in confidence and not to disclose the same to any other person or organisation during the life of this agreement or thereafter (excepting always as may be required by law) without the written consent of *GLAXO* and *J & J* hereby agrees that the Know-how and the confidential information aforesaid is and shall at all times remain the property of *GLAXO* and *J & J* undertakes on the effective termination of this agreement in accordance with Clause 11 hereof to cease using the same and if *GLAXO* shall so request to return to *GLAXO* all documents relating thereto and all copies or reproductions thereof providing that the provisions of this Clause shall not apply to any part of the Know-how or confidential information aforesaid as shall have passed into the public domain .....

(b) *J & J* assumes complete responsibility for the success or lack of success of its operations hereunder and *GLAXO* makes no guarantees or representations concerning the Know-how or other information to be supplied hereunder or concerning the effectiveness operability or economy of any process or product which may be disclosed to *J & J* hereunder .....

PATENTS 8.

(a) *J & J* undertakes during the continuance of this agreement (and thereafter in the event of the termination of this agreement in accordance with the provisions of Clause 11(c) hereof) not to attack or to be concerned or to permit its affiliates to be concerned in any attack directly or indirectly on any patents or patent applications at any time the subject of this agreement or any patents or patent applications owned by *GLAXO* or *I.C.I.* in countries foreign to the countries the subject of this agreement equivalent or corresponding thereto or the subject matter of which is in

any way concerned with griseofulvin or preparations containing the same

(b) No licence immunity or indemnity is hereby granted to *J & J* or to be implied under or against any patent of any third party and *GLAXO* makes no guarantees or representations concerning the patents of others or concerning the application or lack of application of any such patent to any operation which *J & J* or its Affiliates may conduct hereunder .....

(c) If at any time during the continuance of this agreement either party shall become aware of any infringement or threatened infringement of any of the Schedule A Patents or Schedule B Patents the party having knowledge thereof shall forthwith give notice thereof to the other and the parties shall thereupon consult together as to the action to be taken. If in such event *GLAXO* or *I.C.I.* shall not be willing to take legal proceedings against any infringer then subject to the written consent of the owner of the patent involved (*I.C.I.* or *GLAXO* as the case may be) which consent shall not be unreasonably withheld *J & J* may at its own exepense take such proceedings and in such case any damages recovered shall belong to *J & J*. For the purpose of such proceedings *GLAXO* and/or *I.C.I.* shall permit, if such be legally necessary, the use of its name and shall execute such documents and do such acts as may be necessary and *J & J* shall indemnify *GLAXO* and *I.C.I.* against all costs damages and expenses occasioned thereby. *J & J* shall furthermore keep *GLAXO* and/or *I.C.I.* as the case may be informed of the progress of such proceedings .....

IMPROVEMENTS 9.

(a) If during the continuance of this agreement *GLAXO* shall make discover or acquire in relation to the production of griseofulvin and preparations containing the same (for human and veterinary use including animal feeding) any invention whether patented or not or any process relating to or derived from or any improvements upon the Know-how *GLAXO* shall unless prevented by the terms of any such acquisition communicate the same to *J & J* and thereby authorise *J & J* and Affiliates to make use and sell griseofulvin and preparations containing the same thereunder and/or in accordance therewith during the continuance of and in accordance with this agreement without payment

additional to that provided in Clause 4 hereof provided always that if such rights shall only have been acquired by *GLAXO* subject to payment *GLAXO* shall be entitled to request *J & J* and *J & J* shall if it shall desire to be entitled to such rights pay to *GLAXO* a fair proportion (which proportion shall be agreed between the parties hereto) .....

(b) If during the continuance of this agreement *J & J* shall make discover or acquire in relation to the production of griseofulvin and preparations containing the same (for human and veterinary use including animal feeding) any invention whether patented or not or any process relating to or derived from or any improvement upon the Know-how *J & J* shall unless prevented by the terms of any such acquisition communicate the same to *GLAXO* and thereby authorise *GLAXO* and its Associated Companies and (in so far as the same shall relate to the Schedule B Patents) *I.C.I.* and its Associated Companies (and subject to *J & J's* express consent any body corporate or unincorporate which shall be licensed or sublicensed by *GLAXO* to make use and sell griseofulvin) to make use and sell griseofulvin and preparations containing the same thereunder and/or in accordance therewith during the continuance of this agreement without payment *PROVIDED ALWAYS* that if such rights shall only have been acquired by *J & J* subject to payment *J & J* shall be entitled to request from *GLAXO* and *I.C.I.* and *GLAXO* and *I.C.I.* shall if either shall desire to be entitled to have such rights pay to *J & J* a fair proportion (which proportion shall be agreed between the parties hereto) .....

(c) At least one year prior to the expiration of this agreement (as provided for in Clause 6 hereof) *GLAXO* and *J & J* shall consider together whether either party wishes to retain the rights obtained under Clauses 9(a) and 9(b) beyond the life of this agreement and if so on what terms they shall be permitted to do so. In respect of any rights obtained by *I.C.I.* under Clause 9(b) of this agreement *J & J* shall likewise consider together with *I.C.I.* .....

TRADEMARK AND GET-UP 10.

J & J undertakes not to use and not to permit any Affiliate to use on any product sold hereunder any trademark name or designation likely to be confused with any trademark name or designation used by *GLAXO* or *I.C.I.* or any of

their Associated Companies and further undertakes not to use knowingly or intentionally a get-up for any such product likely to be confused with those of *GLAXO* or *I.C.I.* or any of their Associated Companies unless otherwise agreed in writing by the parties hereto .....

TERMINATION 11.

(a) In the event that either party defaults or breaches any of the provisions of this agreement other than by reason of Force Majeure the other party shall have the right to terminate this agreement by giving written notice to the defaulting party provided however that in the case of a default or breach capable of being made good if the said defaulting party shall make good the said default or breach within sixty days after said notice shall have been given then the said notice shall not be effective .....

(b) If *J & J* shall become insolvent or shall make an assignment for the benefit of creditors or proceedings in voluntary or involuntary bankruptcy shall be instituted on behalf of or against *J & J* or a Receiver or Trustee of *J & J's* property shall be appointed this agreement shall without further action or notice forthwith terminate .....

(c) At any time after five years from the date first above written *J & J* shall have the right to terminate this agreement by giving twelve calendar months' written notice thereof to *GLAXO* .....

(d) The expiration or sooner termination of this agreement shall be without prejudice to the obligation of *J & J* to pay *GLAXO* all royalties accrued due and payable under Clause 4 hereof to the obligation of *J & J* to preserve the secret and confidential nature of the Know-how and any information conveyed by *GLAXO* under the provisions of Clause 9(a) hereof for so long as it shall not be in the public domain and to any other right of or remedy available to either party at such expiration or sooner termination .....

(e) Upon the termination of this agreement by *GLAXO* *J & J* shall notify *GLAXO* of the amount of griseofulvin and preparations containing the same in stock and not sold by *J & J* and Affiliates at the effective date of such termination and *J & J* and Affiliates shall be permitted to sell that amount of such griseofulvin and preparations containing the same but no more providing *J & J* shall pay to *GLAXO* the royalties thereon at the rate and in the manner hereinbefore provided .....

WAIVER 12.

The failure on the part of either of the parties hereto to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right nor operate to bar the exercise or enforcement thereof at any time or times thereafter .....

MOST FAVOURED LICENCEE 13.

In the event that *GLAXO* substantially only in consideration for a cash royalty shall hereafter make an agreement with any Independent Third Party covering any of the territories the subject of this agreement on terms and conditions similar to these contained herein but at a royalty rate less than that provided herein then such more favourable royalty rate shall apply to *J & J* in the territories concerned with effect from the date on which it becomes operative for the said Independent Third Party .....

INTERPRETATION 14.

This Agreement is to be construed and take effect as a contract made in England and in accordance with the Laws of England .....

ARBITRATION 15.

Any dispute, controversy or claim arising out of or relating to any of the provisions of this agreement or the breach thereof shall be settled by arbitration. Each party shall appoint one arbitrator and these appointees shall with all reasonable speed appoint a third arbitrator but in default of agreement by such appointees the third arbitrator shall be nominated at the request of either appointee by the President for the time being of the Anglo American Chamber of Commerce. The rules of procedure and any other matters calling for decision by the arbitrators shall be by a majority. If the arbitration proceeding is initiated by *GLAXO* it shall take place in New Brunswick New Jersey U.S.A. and if the said proceeding is initiated by *J & J* it shall take place in London England. The decision of the arbitrators shall be accepted as final and binding upon both parties. .....

NOTICES 16.

Any notice or consent required to be given by either party hereunder shall be given by letter addressed to the party for whom it is intended at the address set forth in the preamble to this agreement or at such other address as such party may designate in writing. Any such notice or consent shall be deemed to have been given when it would have been delivered in the ordinary course of post. .....

TITLES 17.

It is agreed by the parties hereto that the marginal headings herein and the list of contents have been inserted for convenience only and do not constitute any part of this agreement .....

SCHEDULE A hereinbefore referred to
(Continued)

Country	Serial or Application Number	Patent Number
United States of America	573621	2843527
	582927	2938835
	592270	3008876
	631993	2986496

SCHEDULE B hereinbefore referred to

Country	Serial or Application Number	Patent Number
Brazil	97204	
	97205	
Mexico	48890	
	48892	
United States of America	681472	
	681473	

SCHEDULE C hereinbefore referred to

Johnson & Johnson de Argentina, S.A.C. e I.
Darwin 471
Buenos Aires, Argentina.

Johnson & Johnson do Brasil
Av. do Estado 8459
Sao Paulo, Brasil

McNeil Laboratories of Canada Limited,
357 College Street,
Toronto, Canada.

McNeil de Mexico, S.A. de C.V.
Ave. Horacio 603
Mexico, D.F., Mexico.

McNeil Laboratories Inc.,
2900 North 17th Street,
Philadelphia, Pennsylvania, U.S.A.

EXHIBIT 23, ANNEXED TO WALLACE AFF'T. OF JUNE 13, 1969—AGREEMENT BETWEEN SCHERING CORPORATION AND GLAXO LABORATORIES LIMITED, DATED APRIL 1, 1959

An AGREEMENT made the 1st day of April, One thousand nine hundred and fifty-nine *BETWEEN SCHERING CORPORATION* a corporation organised and existing under the Laws of the State of New Jersey United States of America and having its principal place of business at 60 Orange Street Bloomfield New Jersey United States of America (hereinafter referred to as "*SCHERING*") and *GLAXO LABORATORIES LIMITED* a Company organised and existing under the Laws of England and having its registered office at 891-995 Greenford Road Greenford Middlesex England (hereinafter referred to as "*GLAXO*")

WITNESSETH THAT WHEREAS

(A) *GLAXO* is the owner of the patents and patent applications listed in Schedule A hereto (the said patents and patent applications and any patents granted thereon and any continuations reissues and extensions of any of the same shall hereinafter be referred to as the "Schedule A Patents") all of which relate to the production of griseofulvin and preparations containing the same and is the owner of valuable technical and other confidential information relating thereto not disclosed in the Schedule A Patents (all such information for so long as it shall remain confidential to *GLAXO* and its licensees and sublicensees shall be referred to hereinafter as the "Know-how") .....

(B) *IMPERIAL CHEMICAL INDUSTRIES LIMITED* (hereinafter referred to as I.C.I.) a company organised and existing under the Laws of England and having its registered office at Imperial Chemical House Millbank London England is the owner of the patent applications listed in Schedule B hereto (which patent applications and any patents granted thereon and any continuations reissues and extensions thereof shall hereinafter be referred to as the "Schedule B Patents") relating to griseofulvin preparations and has by arrangement with *GLAXO* authorised and empowered *GLAXO* to grant non-exclusive sublicences thereunder .....

(C) *SCHERING* desires to have licences under the Schedule A Patents and sublicences under the Schedule B Patents and to receive and be authorised to use the Know-how to make or have made and use and sell griseofulvin and preparations containing the same and furthermore desires to purchase griseofulvin in bulk from *GLAXO* to use and sell .....

(D) *GLAXO* is willing to grant such licences and sublicences and to provide and authorise such use of the Know-how and to meet so far as it is able any requests from *SCHERING* for the supply of griseofulvin in bulk upon the terms and conditions hereinafter set forth .....

NOW THEREFORE IT IS HEREBY AGREED by and between the parties thereto as follows: .....

DEFINITIONS 1.

Wherever the following expressions are used in this agreement they shall have the meaning specified below unless otherwise expressly provided or repugnant to the context .....

(a) "Affiliates" means such companies associated with *SCHERING* as are listed in Schedule C hereof or may hereafter be listed therein by mutual written agreement ...

(b) "Associated Companies" means those companies all of whose activities shall be controlled by *GLAXO* or *I.C.I.* as the case may be by ownership of the majority of the voting rights or by other means .....

(c) "Independent Third Party" means any person or organisation corporate or unincorporate other than *SCHERING* or Affiliates *GLAXO* or its Associated Companies and I.C.I. or its Associated Companies .....

(d) "Net Sales" during any calendar quarter means

(i) in the case of griseofulvin sold by *SCHERING* and/or Affiliates as such or compounded with any material for which no prophylactic therapeutic or nutritional effect is expressly claimed by *SCHERING* or Affiliates the net proceeds of sales after deducting all normal and customary trade and quantity discounts and allowances granted to customers excise or other sales taxes which *SCHERING* and/or Affiliates have to pay or absorb on such sales and .....

(ii) in the case of griseofulvin sold by *SCHERING*

and/or Affiliates compounded with any material for which *SCHERING* or Affiliates expressly claim a prophylactic therapeutic or nutritional effect, the value of the total declared amount of the griseofulvin contained therein calculated at the average price per gramme of griscofulvin obtained by dividing Net Sales made in accordance with Clause 1(d)(i) hereof for the quarter in question by the number of grammes of griseofulvin represented by the said Net Sales. .....
PROVIDED ALWAYS that solely for the purpose of calculating net sales hereunder human medical sales, veterinary medical sales and animal feed sales, shall be treated separately .....

(c) "Force Majeure" means requisition or interference by any Government State or local authority war strikes lock-outs riot or epidemic diseases Act of God or any other circumstances whatsoever whether eiusdem generis to the above causes or not over which *SCHERING* or *GLAXO* as the case may be shall have no control .....

(f) The singular shall include the plural and vice versa

LICENCE GRANT 2.

(a) *GLAXO* hereby warrants that it is authorised and enpowered by I.C.I. to grant non-exclusive sub-licences under the Schedule B Patents .....

(b) *GLAXO* hereby undertakes on receipt of a written request from *SCHERING* to transmit the Know-how to *SCHERING* and *GLAXO* hereby grants to *SCHERING* and Affiliates sub-licences under the Schedule B Patents and licences and rights under the Schedule A Patents and the Know-how to make griseofulvin in the United States of America (subject always to any provisions in respect thereof hereinafter set forth) and to use and sell griseofulvin and to make use and sell preparations containing the same for human and veterinary use (including animal feeding) in Argentina Bolivia Brazil Canada Chile Costa Rica Equador El Salvador Formosa Guatemala Republic of Honduras Japan Mexico Nicaragua Panama Paraguay Peru Phillippines Uruguay United States of America and Venezuela and the territories possessions and dependencies of any of the same at the date hereof provided that (except in circumstances where an Independent Third Party is selling griseofulvin without *GLAXO's* consent express or im-

plied) *SCHERING* and Affiliates shall not sell griseofulvin in Argentina Brazil Canada Equador Mexico Peru Uruguay or Venezuela until ninety days after the date (which *GLAXO* shall promptly indicate to *SCHERING* in each case) on which *GLAXO's* subsidiary company or agent in that country shall have made its first commercial sale of griseofulvin. All sublicences licences and rights granted hereunder shall be non-exclusive non-transferable non-divisible and non-sublicensable save that *SCHERING* shall be entitled (subject to any provisions in this agreement in respect thereof and subject to *GLAXO's* express approval in writing which approval shall not be unreasonably withheld)

(i) to have griseofulvin made for it in the United States of America for use and sale by it and Affiliates in accordance with this Agreement .....

(ii) to make or have griseofulvin made for it in any territory the subject of this agreement outside the United States of America for use and sale by it and Affiliates in accordance with this agreement in circumstances where for commercial reasons affecting such a territory such local manufacture of griseofulvin shall be necessary .....

In the event that *GLAXO* shall indicate to *SCHERING* that the purchase of griseofulvin manufactured by or on behalf of *SCHERING* hereunder is desired by *GLAXO* or *I.C.I.* or Associated Companies of either of the same for resale *SCHERING* undertakes to use its best endeavours to meet such desires .....

(c) *SCHERING* shall under the sublicences licences and rights herein granted .....

(i) distribute griseofulvin and preparations containing the same solely under its own corporate name or those of its Affiliates .....

(ii) advise *GLAXO* within a reasonable time after the execution of this agreement as to the specific trade names marks or designations under which it will render bills covering the sale of griseofulvin and preparations containing the same and keep *GLAXO* informed of any changes or new trade names marks or designations which it may thereafter make or adapt for griseofulvin

and preparations containing the same and in rendering bills therefor invariably use the trade names marks and designations so furnished to *GLAXO*

(iii) give written notice to *GLAXO* at least nine calendar months prior to the date of the first commercial production of griseofulvin by it or on its behalf in any territory the subject of this agreement and acquaint *GLAXO* fully with the intended scale of such production at that date and for at least the twelve calendar months subsequent thereto .....

(iv) give written notice to *GLAXO* at least nine calendar months prior to obtaining for resale by it or Affiliates griseofulvin manufactured by any Independent Third Party authorized directly or indirectly by *GLAXO* so to do .....

PROVIDED ALWAYS that *SCHERING* shall not be required to give the notices referred to in paragraphs (iii) and (iv) of this Clause 2(c) in the event that *GLAXO* shall not be able fully to meet such reasonable orders for griseofulvin as shall be placed by *SCHERING* in accordance with the provisions of Cluase 3 hereof .....

BULK SUPPLIES 3.

(a) Save for such griseofulvin of *SCHERING* and Affiliates shall acquire from manufacture by or on behalf of *SCHERING* or by any Independent Third Party authorised directly or indirectly by *GLAXO* so to do within the territories the subject of this agreement *SCHERING* shall seek to purchase all the requirements of *SCHERING* and Affiliates for griseofulvin from *GLAXO* at such reasonable prices as the parties hereto shall agree in respect thereof. At least ninety days prior to the beginning of each calendar quarter *SCHERING* shall order from *GLAXO* its and Affiliates requirements for each month of such calendar quarter specifying quality delivery dates and quantities desired and *GLAXO* shall indicate within ten days of the receipt of any such order whether and to what extent it shall be able to meet the same. Delivery shall be made by *GLAXO* to such address as *SCHERING* shall direct but *SCHERING* shall pay the landing charges and customs duties and shall reimburse *GLAXO* for the cost of insurance on such shipments. If any quantity for griseofulvin supplied by *GLAXO* here-

under is found by *SCHERING* not to be of the quality specified by *SCHERING SCHERING* shall have the right to return it to *GLAXO* at *GLAXO's* expense provided that notice of *SCHERING's* intention to return it is given by *SCHERING* to *GLAXO* within thirty days after the date of receipt of such quality at such address aforesaid and that such quantity is actually returned to *GLAXO* within thirty days after the giving of such notice. In the event that in lieu of the return of such quantity *SCHERING* shall elect to reprocess the same *SCHERING* shall be entitled to reimbursement from *GLAXO* of the reasonable cost of such reprocessing which cost shall not exceed the expense *GLAXO* would have incurred if such quantity had been returned as aforesaid

(b) In order to assist *GLAXO* in its production planning *SCHERING* agrees to furnish *GLAXO* at least sixty days prior to the beginning of each calendar year of this agreement with a written estimate of its and Affiliates requirements of griseofulvin from *GLAXO* for such calendar year provided always that *SCHERING* shall incur no liability in the event its and Affiliates actual requirements for any such calendar year shall fail to equal the written estimate therefor nor shall *SCHERING's* right to order griseofulvin from *GLAXO* hereunder be limited to any such written estimate

(c) *SCHERING* undertakes not to sell or to permit its Affiliates to sell any griseofulvin in bulk to any Independent Third Party without *GLAXO's* express consent in writing.

ROYALTY 4.

During the life of this agreement *SCHERING* shall pay to *GLAXO* in the manner provided in Clause 5 hereof .....

(i) a royalty of 2½% (two and a half percentum) on Net Sales of all griseofulvin supplied by or on behalf of *GLAXO*

(ii) a royalty of 2½% (two and a half percentum) on Net Sales of all griseofulvin manufactured by or on behalf of *SCHERING* or by any Independent Third Party authorised so to do by *GLAXO* in the manufacture of which is used all or any part of the Know-how and/or any confidential information conveyed by *GLAXO* under the provisions of Clause 9(a) hereof and

(iii) a royalty of 5% (five percentum) on Net Sales of

all griseofulvin manufactured by or on behalf of *SCHERING* or by any Independent Third Party authorised so to do by *GLAXO* the whole or any part of the manufacture formulation use or sale of which is embraced by any of the claims of any of the Schedule A Patents or Schedule B Patents or any patents or patent applications under which *SCHERING* shall be given rights under the provisions of Clause 9(a) hereof which exist in the territory of such manufacture formulation use or sale

(iv) Upon the request of *SCHERING GLAXO* and *SCHERING* will confer with respect to a possible reduction in the royalties reserved hereunder in respect of sales in any country in the event that *SCHERING* shall demonstrate that the royalties herein reserved are having a detrimental effect on *SCHERING's* ability competitively to market griseofulvin and preparations containing the same in such country or in the event that by reason of any operations hereunder *SCHERING* shall find itself liable to pay a royalty to any third party .....

(v) Nothing contained herein shall obligate *SCHERING* to pay royalty upon transactions between it, Affiliates or any licencees or sublicencees of *GLAXO* or to pay royalty more than once on sales of griseofulvin or preparations containing the same .....

ACCOUNTING 5.

(*a*) *SCHERING* shall keep true and particular accounts of all royalties payable under Clause 4 hereof and shall deliver to *GLAXO* written statements thereof on or before the sixtieth day following the end of each calendar quarter (or any part thereof in the first or last calendar quarter) of this agreement indicating the amount of griseofulvin sold in each country and at the same time shall pay to *GLAXO* or to whomsoever *GLAXO* shall otherwise direct in United States currency available in London England the amount due and payable as reported in any given statement. .....

(*b*) *GLAXO* shall have the right to have a public accountant of its own selection and at its own expense except one to whom *SCHERING* may have reasonable objection to examine the relevant accounts of *SCHERING* for a period of not more than two complete accounting years immediately

preceding the date of review to determine whether appropriate accounting and payment has been made .....

TERM 6.

This agreement shall unless sooner terminated continue in full force and effect for Seventeen years from the date first above written or until the expiration of the last to expire of the Schedule A Patents and the Schedule B Patents whichever shall be the later

KNOW-HOW 7.

(*a*) *SCHERING* hereby undertakes to bind all its agents employees and any independent parties under contract to it for any reason whatsoever having access to any of the Know-how or any confidential information conveyed by *GLAXO* under the provisions of Clause 9(a) hereof to hold the same in confidence and not to disclose the same to any other person or organisation during the life of this agreement or thereafter (excepting always as may be required by law) without the written consent of *GLAXO* and *SCHERING* hereby agrees that the Know-how and the confidential information aforesaid is and shall at all times remain the property of *GLAXO* and *SCHERING* undertakes on the effective termination of this agreement in accordance with Clause 11 hereof to cease using the same and if *GLAXO* shall so request to return to *GLAXO* all documents relating thereto and all copies or reproductions thereof providing that the provisions of this Clause shall not apply to any part of the Know-how or confidential information aforesaid as shall have passed into the public domain .....

(*b*) *SCHERING* assumes complete responsibility for the success or lack of success of its operations hereunder and *GLAXO* makes no guarantees or representations concerning the Know-how or other information to be supplied hereunder or concerning the effectiveness operability or economy of any process or product which may be disclosed to *SCHERING* hereunder

PATENTS 8.

(*a*) *SCHERING* undertakes during the continuance of this agreement (and thereafter in the event of the termina-

tion of this agreement in accordance with the provisions of Clause 11(c) hereof not to attack or to be concerned or to permit its Affiliates to be concerned in any attack directly or indirectly on any patents or patent applications at any time the subject of this agreement or any patents or patent applications owned by *GLAXO* or *I.C.I.* in countries foreign to the countries the subject of this agreement equivalent or corresponding thereto or the subject matter of which is in any way concerned with griseofulvin or preparations containing the same .....

(b) No licence immunity or indemnity is hereby granted to *SCHERING* or to be implied under or against any patent of any third party and *GLAXO* makes no guarantees or representations concerning the patents of others or concerning the application or lack of application of any such patent to any operation which *SCHERING* or its Affiliates may conduct hereunder .....

(c) If at any time during the continuance of this agreement either party shall become aware of any infringement or threatened infringement of any of the Schedule A Patents or Schedule B Patents the party having the knowledge thereof shall forthwith give notice thereof to the other and the parties shall thereupon consult together as to the action to be taken. If in such event *GLAXO* or *I.C.I.* shall not be willing to take legal proceedings against any infringer then subject to the written consent of the owner of the patent involved (*I.C.I.* or *GLAXO* as the case may be) which consent shall not be unreasonably withheld *SCHERING* may at its own expense take such proceedings and in such case any damages recovered shall belong to *SCHERING*. For the purpose of such proceedings *GLAXO* and/or *I.C.I.* shall permit, if such be legally necessary, the use of its name and shall execute such documents and do such acts as may be necessary and *SCHERING* shall indemnify *GLAXO* and *I.C.I.* against all costs damages and expenses occasioned thereby. *SCHERING* shall furthermore keep *GLAXO* and/or *I.C.I.* as the case may be informed of the progress of such proceedings. .....

IMPROVEMENTS. 9.

(a) If during the continuance of this agreement *GLAXO* shall make discover or acquire in relation to the production of griseofulvin and preparations containing the same (for

human and veterinary use including animal feeding) any invention whether patented or not or any process relating to or derived from or any improvements upon the Know-how *GLAXO* shall unless prevented by the terms of any such acquisition communicate the same to *SCHERING* and thereby authorise *SCHERING* and Affiliates to make use and sell griseofulvin and preparations containing the same thereunder and/or in accordance therewith during the continuance of and in accordance with this agreement without payment additional to that provided in Clause 4 hereof provided always that if such rights shall only have been acquired by *GLAXO* subject to payment *GLAXO* shall be entitled to request *SCHERING* and *SCHERING* shall if it shall desire to be entitled to such rights pay to *GLAXO* a fair proportion (which proportion shall be agreed between the parties hereto) .....

(b) If during the continuance of this agreement *SCHERING* shall make discover or acquire in relation to the production of griseofulvin and preparations containing the same (for human and veterinary use including animal feeding) any invention whether patented or not or any process relating to or derived from or any improvement upon the Know-how *SCHERING* shall unless prevented by the terms of any such acquisition communicate the same to *GLAXO* and thereby authorise *GLAXO* and its Associated Companies and (in so far as the same shall relate to the Schedule B Patents) *I.C.I.* and its Associated Companies (and subject to *SCHERING's* express consent any body corporate or unincorporate which shall be licensed or sublicensed by *GLAXO to make* use and sell griseofulvin) to make use and sell griseofulvin and preparations containing the same thereunder and/or in accordance therewith during the continuance of this agreement without payment *PROVIDED ALWAYS* that if such rights shall only have been acquired by *SCHERING* subject to payment *SCHERING* shall be entitled to request from *GLAXO* and *I.C.I.* and *GLAXO* and *I.C.I.* shall if either shall desire to be entitled to have such rights pay to *SCHERING* a fair proportion (which proportion shall be agreed between the parties hereto) .....

(c) At least one year prior to the expiration of this agreement (as provided for in Clause 6 hereof) *GLAXO* and *SCHERING* shall consider together whether either

party wishes to retain the rights obtained under Clauses 9(a) and 9(b) beyond the life of this agreement and if so on what terms they shall be permitted to do so. In respect of any rights obtained by *I.C.I.* under Clause 9(b) of this agreement *SCHERING* shall likewise consider together with I.C.I. .....

TRADE MARKS AND GET-UP. 10

SCHERING undertakes not to use and not to permit any Affiliate to use on any product sold hereunder any trademark name or designation likely to be confused with any trade mark name or designation used by *GLAXO* or *I.C.I.* or any of their Associated Companies and further undertakes not to use knowingly or intentionally a get-up for any such product likely to be confused with those of *GLAXO* or *I.C.I.* or any of their Associated Companies unless otherwise agreed in writing by the parties hereto .....

TERMINATION 11.

(a) In the event that either party defaults or breaches and of the provisions of this agreement other than by reason of Force Majeure the other party shall have the right to terminate this agreement by giving written notice to the defaulting party provided however that in the case of a default or breach capable of being made good if the said defaulting party shall make good the said default or breach within sixty days after said notice shall have been given then the said notice shall not be effective.

(b) *If SCHERING* shall become insolvent or shall make an assignment for the benefit of creditors or proceedings in voluntary or involuntary bankruptcy shall be instituted on behalf of or against *SCHERING* or a Receiver or Trustee of *SCHERING's* property shall be appointed this agreement shall without further action or notice forthwith terminate.

(c) At any time after five years from the date first above written *SCHERING* shall have the right to terminate this agreement by giving twelve calendar months' written notice thereof to *GLAXO* .....

(d) The expiration or sooner termination of this agreement shall be without prejudice to the obligation of *SCHERING* to pay *GLAXO* all royalties accrued due and payable under Clause 4 hereof to the obligation of *SCHER-*

ING to preserve the secret and confidential nature of the Know-how and any information conveyed by *GLAXO* under the provisions of Clause 9(a) hereof for so long as it shall not be in the public domain and to any other right of or remedy available to either party at such expiration or sooner termination .....

(e) Upon the termination of this agreement by *GLAXO* *SCHERING* shall notify *GLAXO* of the amount of griseofulvin and preparations containing the same in stock and not sold by *SCHERING* and Affiliates at the effective date of such termination and *SCHERING* and Affiliates shall be permitted to sell that amount of such griseofulvin and preparations containing the same but no more providing *SCHERING* shall pay to *GLAXO* the royalties thereon at the rate and in the manner hereinbefore provided .....

WAIVER 12.

The failure on the part of either of the parties hereto to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right nor operate to bar the exercise or enforcement thereof at any time or times thereafter .....

MOST FAVOURED LICENCEE 13.

In the event that *GLAXO* substantially only in consideration for a cash royalty shall hereafter make an agreement with any Independent Third Party covering any of the territories the subject of this agreement on terms and conditions similar to those contained herein but at a royalty rate less than that provided herein then such more favourable royalty rate shall apply to *SCHERING* in the territories concerned with effect from the date on which it becomes operative for the said Independent Third Party.

INTERPRETATION 14.

This agreement is to be construed and take effect as a contract made in England and in accordance with the Laws of England .....

ARBITRATION 15.

Any dispute, controversy or claim arising out of or relating to any of the provisions of this agreement or the breach there shall be settled by arbitration. Each party shall appoint one arbitrator and these appointees shall with all rea-

sonable speed appoint a third arbitrator but in default of agreement by such appointees the third arbitrator shall be nominated at the request of either appointee by the President for the time being of the Anglo American Chamber of Commerce. The rules of procedure and any other matters calling for decision by the arbitrators shall be by a majority. If the arbitration proceeding is initiated by *GLAXO* it shall take place in New Brunswick New Jersey U.S.A. and if the said proceeding is initiated by *SCHERING* it shall take place in London England. The decision of the arbitrators shall be accepted as final and binding upon both parties. .....

NOTICES 16.

Any notice or consent required to be given by either party hereunder shall be given by letter addressed to the party for whom it is intended at the address set forth in the preamble to this agreement or at such other address as such party may designate in writing. Any such notice or consent shall be deemed to have been given when it would have been delivered in the ordinary course of post. .....

TITLES 17.

It is agreed by the parties hereto that the marginal headings herein and the list of contents have been inserted for convenience only and do not constitute any part of this agreement .....

IN WITNESS whereof the parties hereto have caused this agreement to be duly signed and sealed as of the day and year first above written .....

THE COMMON SEAL of *GLAXO LABORATORIES LIMITED* was hereunto affixed in the presence of:

Director.

Director.

Secretary.

Director.

Director.

Secretary.

SCHEDULE A hereinbefore referred to

Country	Serial or Application Number	Patent Number
Argentina		105524
		108203
Brazil	85566	
	86530	
Canada	703774	
	706845	
	709085	
	720595	
Japan	31–7765	
	12880/56	
	31–16246	
	31–32730	
United States of America		2843527
	582927	
	592270	
	631993	
	662985	

SCHEDULE B hereinbefore referred to

Country	Serial or Application Number	Patent Number
Brazil	97204	
	97205	
Mexico	48890	
	48892	
United States of America	681472	
	681473	

SCHEDULE C hereinbefore referred to.

Essex (Argentina) S.A.I.C.,
Argentina.
Industria Quimica e Farmaceutica Schering, S.A.,
Brazil.

Pharmaco (Canada) Ltd.,
Canada.
Schering Corporation Limited,
Canada.
White Laboratories of Canada Limited,
Canada.
Schering Compania Limitada,
Chile.
Schering Corporation International, S.A.,
Panama.
Schering Corporation (Panama) S.A.,
Panama.
Schering Corporation Pan America, S.A.,
Panama.
Schering Corporation del Peru, S.A.,
Peru.
American Scientific Laboratories Incorporated,
U.S.A.
Pharmaco, Inc.,
U.S.A.
White Laboratories, Inc.,
U.S.A.
Essex (Uruguay) S.A.,
Uruguay.
Schering Corporation de Venezuela, S.A.
Venezuela.

EXHIBIT 10, ANNEXED TO BOHLING AFFT. OF JULY 7, 1970

FROM M. J. Methven,
Legal Department,
IMPERIAL CHEMICAL
HOUSE, MILLBANK,
LONDON, S.W. 1

TO Mr. T. W. M. Bland,
Division Secretary
Pharmaceuticals Division
Fulshaw Hall,
Wilmslow, Cheshire

DATE 14th January, 1960

SUBJECT GRISEOFULVIN—EXCHANGE OF LICENCES WITH GLAXO LABORATORIES LIMITED

Further to my note of yesterday, I have now considered in detail the new draft Agreement between Glaxo and I.C.I. on griseofulvin.

You will remember that you sent to me an earlier draft Agreement relating to griseofulvin on which I made some detailed comments on the 9th July last year. It seems to me that this new draft Agreement still suffers from some of the defects of the earlier one and on which I commented in my earlier letter.

The following are the detailed points which I should like to make to you:

* * * * *

Clause 4—Bulk Supplies

* * * * *

(e) Are you prepared to accept the obligation contained in this Clause? *

* * * * *

* Handwritten notation: Yes.

EXHIBIT 11, ANNEXED TO BOHLING AFFT. OF JULY 7, 1970

FROM [T. W. M. Bland]
The Secretary
[ICI]

[TO] I.C.I. Legal Department,
I.C. House, London.
Mr. M. J. Methven.

[DATE] 21st January, 1960.

GRISEOFULVIN—EXCHANGE OF LICENCES WITH GLAXO LABORATORIES LIMITED

Thank you for your letter of 14th January. I hope that the explanation that we gave you yesterday served to clarify some of the points on this draft agreement about which you were in doubt. However, I think that I should nevertheless place on the record our replies to the points made in your letter. These are as follows:—

* * * * *

Clause 4—Bulk Supplies

* * * * *

e) We are willing to accept the obligation contained in this clause—Glaxo are imposing a similar obligation on all their licensees.

* * * * *

As agreed with you yesterday, we will discuss the points referred to above next Wednesday afternoon after the Interferon meeting. As I told you, we are anxious to get this agreement completed as quickly as possible and, in the hope that so far as the Company is concerned we shall be able on Wednesday to settle the terms of the draft, Dr. Cusa and I have provisionally arranged to meet Glaxo either later that afternoon or on Thursday morning. We hope that it will then be possible to reach finality with Glaxo.

[illegible handwritten notation]

T. W. M. BLAND

EXHIBIT 3, ANNEXED TO WALLACE AFFT. OF OCT. 31, 1968—AGREEMENT BETWEEN GLAXO AND ICI, DATED APRIL 26, 1960

THE AGREEMENT made this 26th day of April One Thousand nine hundred and sixty between IMPERIAL CHEMICAL INDUSTRIES LIMITED whose registered office is situated at Imperial Chemical House Millbank London S.W.1. (hereinafter referred to as "I.C.I.") of the one part and GLAXO LABORATORIES LIMITED whose registered office is situated at 891-995 Greenford Road Greenford Middlesex (hereinafter referred to as "GLAXO") of the other part

WITNESSETH THAT WHEREAS:

(A) I.C.I. is the owner of the patents and patent applications listed in Schedule A hereto (the said patents and patent applications and any patents granted thereon and any continuations reissues and extensions of any of the same shall hereinafter be refererred to as the "I.C.I. Patents") relating to preparations containing griseofulvin and to methods of using griseofulvin in man and in animals .....

(B) GLAXO is the owner of the patents and patent applications listed in Schedule B hereto (the said patents and patent applications and any patents granted thereon and any continuations reissues and extensions of any of the same shall hereinafter be referred to as the "Glaxo Patents") relating to the production of griseofulvin preparations containing the same and is the owner of valuable technical and other confidential information relating to griseofulvin not disclosed in the Glaxo patents (all such information for so long as it shall remain confidential to GLAXO and its licensees and sublicensees shall be referred to hereinafter as the "Know-how") .....

(C) I.C.I. desires to have licences under the Glaxo Patents and to receive and be authorised to use the Know-how to make use and sell griseofulvin and preparations containing the same and furthermore desires to purchase griseofulvin in bulk from GLAXO to use and sell .....

(D) GLAXO desires to have licences under the I.C.I. Patents to make use and sell griseofulvin and preparations containing the same .....

(E) GLAXO and I.C.I. are willing to meet the desires of the other upon the terms and conditions hereinafter set forth .....

NOW THEREFORE IT IS HEREBY AGREED by and between the parties hereto as follows: .....

1. DEFINITIONS.

Wherever the following expressions are used in this Agreement they shall have the meaning specified below unless otherwise expressly provided or repugnant to the context .....

(a) "Subsidiaries" means those companies which in terms of Section 154 of the Companies Act 1948 are subsidiaries of GLAXO or I.C.I. but without prejudice to the foregoing shall include African Explosives and Chemical Industries Limited of Johannesburg South Africa and Glaxo (Benelux) S.A. of Brussels Belgium and such other companies as the parties may at any time mutually agree

(b) "Associates" means such companies associated with I.C.I. as are listed in Schedule C hereof or may hereafter be listed therein by mutual written agreement.....

(c) "Independent Third Party" means any person or organisation corporate or unincorporate other than GLAXO and its Subsidiaries I.C.I. and its Subsidiaries and Associates .....

(d) "Net Sales Value" during any calendar quarter means the value of all griseofulvin manufactured during any calendar quarter by or on behalf of I.C.I. its Subsidiaries or Associates (other than griseofulvin supplied by or on behalf of GLAXO) calculated at I.C.I.'s average selling price per gram of griseofulvin sold in the calendar quarter in question in the United Kingdom in final packaged form ready for ultimate consumer use and uncompounded with any material for which I.C.I. expressly claims a prophylactic therapeutic nutritional or other specific effect. In arriving at said average selling price appropriate deductions may be made in respect of all normal and customary trade and quantity discounts and allowances granted to customers breakage and spoilage which I.C.I. has to pay or absorb on its sales in the United Kingdom aforesaid .....

(e) "Force Majeure" means requisition or interference by any government or local authority war strikes lockouts riots or epidemic diseases whether eiusdem generis to the

above causes or not over which the parties hereto shall have no control .....

(f) The singular shall include the plural and vice versa.

2. RIGHTS GRANTED TO I.C.I.

(a) GLAXO hereby undertakes to grant to I.C.I. at any time that I.C.I. shall so request licences under the Glaxo Patents to manufacture griseofulvin in the United Kingdom and to use and sell griseofulvin and to make use and sell preparations containing the same throughout the world and GLAXO further undertakes to transmit the Know-how to I.C.I. with the right for I.C.I. and its Subsidiaries and Associates to use the same that is coextensive with the Licenees under Glaxo Patents aforesaid. Nothing contained herein shall be held to permit I.C.I. its Subsidiaries or Associates to sell griseofulvin or preparations containing the same in Japan for any use other than human or veterinary (including animal feeding) .....

(b) The licences and rights referred to in subclause (a) of this clause shall be non-exclusive non-transferable non-divisible and non-sublicensable save that I.C.I. may sublicense its Subsidiaries and Associates hereunder and save that I.C.I. shall be entitled (subject to any provisions in this Agreement in respect thereof and subject to GLAXO's express approval in writing which approval shall not be unreasonably withheld) to make griseofulvin or have griseofulvin made for it in any territory outside the United Kingdom for use and sale by I.C.I. and its Subsidiaries and Associates in accordance with this Agreement in circumstances where for commercial reasons affecting such a territory such local manufacture of griseofulvin shall be necessary for the maintenance or advancement of I.C.I.'s business in griseofulvin in such territory. In the event that GLAXO shall indicate to I.C.I. that the purchase of griseofulvin manufactured by or on behalf of I.C.I. hereunder is desired by GLAXO or its Subsidiaries I.C.I. undertakes to use its best endeavours to meet such desires .....

(c) I.C.I. shall under the licences and rights herein granted distribute griseofulvin and preparations containing the same solely under its own corporate name or those of its Subsidiaries or Associates .....

3. RIGHTS GRANTED TO GLAXO.

(a) I.C.I. hereby undertakes to grant to GLAXO at any time GLAXO shall so request royalty free licences under the I.C.I. Patents to make use and sell griseofulvin and preparations containing the same throughout the world ...

(b) The licences referred to in subclause (a) of this clause shall be exclusive (save for I.C.I.'s right itself to make use and vend under the I.C.I. Patents and for I.C.I.'s right to grant licences thereunder to its Subsidiaries and Associates) sublicensable to GLAXO's Subsidiaries (and subject to I.C.I.'s approval of the terms thereof to Independent Third Parties) non-transferable and non-divisible

4. BULK SUPPLIES.

(a) Save for such griseofulvin as I.C.I. its Subsidiaries and Associates shall make or have made in accordance with this Agreement or shall acquire from manufacture by any Independent Third Party authorised directly or indirectly so to do by GLAXO I.C.I. shall seek to purchase from GLAXO at such reasonable prices as shall be agreed in respect thereof (and subject to Force Majeure GLAXO agrees to supply) all the requirements of I.C.I. and its Subsidiaries and Associates. At least ninety days prior to the beginning of each calendar quarter I.C.I. shall order from GLAXO I.C.I.'s and its Subsidiaries and Associates' requirements for each month of such calendar quarter specifying quality delivery dates and quantities desired and GLAXO shall indicate within ten days of the receipt of any such order whether and to what extent it shall be able to meet the same. Delivery shall be made by GLAXO to such address as I.C.I. shall direct but I.C.I. shall pay any landing charges and customs duties on deliveries which I.C.I. requires to be delivered to addresses outside the United Kingdom. If any quantity of griseofulvin supplied by GLAXO hereunder is found by I.C.I. not to be of the quality specified by I.C.I., I.C.I. shall have the right to demand replacement thereof by material of the quality specified and to return the faulty material to GLAXO at GLAXO's expense provided that notice of I.C.I.'s intention to return it is given by I.C.I. to GLAXO within thirty days after the date of receipt of such quantity and such quantity is actu-

ally returned to GLAXO within thirty days after the giving of such notice. In the event that in lieu of the return of such quantity I.C.I. shall elect to reprocess the same I.C.I. shall be entitled to reimbursement from GLAXO of the reasonable cost of such reprocessing which cost shall not exceed the expense GLAXO would have incurred if such quantity had been returned as aforesaid .....

(b) In order to assist GLAXO in its production planning I.C.I. agrees to furnish GLAXO at least sixty days prior to the beginning of each calendar year of this Agreement with a written estimate of I.C.I.'s and its Subsidiaries and Associates' requirements of griseofulvin from GLAXO for such calendar year provided always that I.C.I. shall incur no liability in the event that I.C.I.'s and its Subsidiaries' and Associates' actual requirements for such calendar year shall fail to equal the written estimate therefor nor shall I.C.I.'s right to order griseofulvin from GLAXO hereunder be limited to any such written estimate .....

(c) It is recognised by the parties hereto that the provisions of Clauses 4(a) and 4(b) hereof as to the timing of orders and estimates the acceptance of orders the giving of notice and the like represent ideals with which both parties will endeavour reasonably to comply. Failure on the part of either I.C.I. or GLAXO to do so however shall not be deemed to be a breach of the terms and conditions of this Agreement .....

(d) In the event that the general demand for griseofulvin exceeds GLAXO's capacity to supply the same GLAXO undertakes that in allocating supplies I.C.I. will be treated no less favorably than any other customer of GLAXO. In any such circumstances the amount allocated to I.C.I. by GLAXO shall not be less than that proportion of the amount available for distribution to GLAXO's several customers (other than GLAXO's Subsidiaries) represented by the mathematical relationship between the average monthly amounts of bulk griseofulvin invoiced by GLAXO to each customer over the preceding twenty-four complete calendar months or over such fewer calendar months as the customer shall have been taking supplies of griseofulvin in bulk from GLAXO .....

(e) I.C.I. undertakes not to sell and to use its best endeavours to prevent its Subsidiaries and Associates from

selling any griseofulvin in bulk to any Independent Third Party without GLAXO's express consent in writing ....

5. *I.C.I. ROYALTY AND ACCOUNTS.*

(a) During the life of this Agreement I.C.I. shall pay to GLAXO in the manner provided in Clause 5(b) hereof on all griseofulvin manufactured hereunder a royalty of 2½% (two and a half percentum) on Net Sales Value as hereinbefore defined .....

(b) I.C.I. shall keep true and particular accounts of all royalties payable under Clause 5(a) hereof and shall deliver to GLAXO written statements thereof on or before the ninetieth day following the end of each calendar quarter (or any part thereof in the first or last calendar quarter) of this Agreement and at the same time shall pay to GLAXO in sterling available in London England the amount due and payable as reported in any given statement .....

(c) GLAXO shall have the right to have a public accountant of its own selection and at its own expense except one to which I.C.I. may have reasonable objection examine the relevant accounts of I.C.I. for a period of not more than two complete accounting years immediately preceding the date of review to determine whether appropriate accounting and payment has been made .....

6. *GLAXO ROYALTY AND ACCOUNTS.*

(a) During the life of this Agreement GLAXO shall pay or shall be responsible for ensuring the payment to I.C.I. (in the manner provided in Clause 6(b) hereof) of one half of the total royalty income deriving solely from the licens-

ing and/or sublicensing of any patents the subject of this Agreement by GLAXO of Independent Third Parties to make use and sell griseofulvin and preparations containing the same for human and veterinary use including animal feeding it being understood and agreed between the parties hereto that such payment to I.C.I. shall in no circumstances represent less than a royalty of 1½% (one and a half per-centum) of net sales of such Independent Third Parties aforesaid. The term net sales for the purposes of this clause shall have the meaning ascribed to it in each license agreement with Independent Third Parties .....

(b) GLAXO shall be responsible for the maintenance by it or its licensees or sublicensees of true and particular accounts of all royalties payable to I.C.I. under Clause 6(a) hereof and shall deliver or have delivered to I.C.I. written statements thereof on or before the ninetieth day following the end of each calendar quarter (or any part thereof in the first or last calendar quarter) of this Agreement and at the same time shall pay or have paid in sterling available in London England the amount due and payable as reported in any given statement PROVIDED ALWAYS that GLAXO shall not be responsible for the payment to I.C.I. of any royalties reported as due and payable in respect of any licensee or sublicensee of GLAXO where the transfer of such royalties from such licensee or sublicensee to the United Kingdom is prohibited by any competent public authority. Such royalties shall accumulate in the local currency for the period during which such prohibition continues but I.C.I. shall have the right to give any proper and legal directions which it may think fit regarding investment or use of any such accumulated royalties. Unless advised to the contrary by I.C.I. GLAXO shall use its best endeavours to obtain the transfer of such royalties as soon as may be possible and pay or have the same paid to I.C.I. notwithstanding that this Agreement may meanwhile have been determined .....

(c) I.C.I. shall have the right to have a public accountant of its own selection and at its own expense except one to whom GLAXO (or its licensees or sublicensees) may have reasonable objection examine the relevant accounts of GLAXO (or its licensees or sublicensees) for a period of not more than two complete accounting years immediately preceding the date of review to determine whether appropriate accounting and payment has been made .....

7. TERM.

This Agreement shall be deemed to have taken effect on 1st January, 1959 and shall unless sooner terminated continue in full force and effect until the first day of January nineteen hundred and seventy four .....

8. SECRECY.

(a) I.C.I. hereby undertakes to take all reasonable steps to ensure that the Know-how and any confidential information conveyed by GLAXO under the provisions of Clause 10(a) hereof shall be kept confidential and shall not be disclosed to any Independent Third Party during the life of this Agreement or thereafter (excepting always as may be required by law) without the written consent of GLAXO and I.C.I. hereby agrees that the Know-how and the confidential information aforesaid are and shall at all times remain the property of GLAXO and I.C.I. undertakes on the effective termination of this Agreement prior to 1st January 1974 by reason of any default or breach by I.C.I. decrease using the same providing that the provisions of this Clause shall not apply to any part of the Know-how or confidential information aforesaid as shall have passed into the public domain .....

(b) GLAXO hereby undertakes to take all reasonable steps to ensure that any confidential information conveyed by I.C.I. under the provisions of Clause 10(b) hereof shall be kept confidential and shall not be disclosed to any Independent Third Party during the life of this Agreement or thereafter (excepting always as may be required by law) without the written consent of I.C.I. and GLAXO hereby agrees that the confidential information aforesaid is and shall at all times remain the property of I.C.I. and GLAXO undertakes on the effective termination of this Agreement prior to 1st January 1974 by reason of any default or breach by GLAXO to cease using the same providing that the provisions of this clause shall not apply to any part of the confidential information aforesaid as shall have passed into the public domain .....

(c) I.C.I. and GLAXO severally assume complete responsibility for the success or lack of success of its own operations hereunder and neither party makes any guarantees or representations concerning the Know-how or other

confidential information to be supplied hereunder or concerning the effectiveness operability or economy of any process or product which may be disclosed hereunder ....

9. *PATENTS.*

(a) The parties hereby undertake not to attack or to be concerned or to permit any Subsidiaries or Associates or any Independent Third Parties licensed or sublicensed in accordance with this Agreement to be concerned directly or indirectly in any attack on any patents or patent applications the subject of this Agreement .....

(b) No licence immunity or indemnity is hereby granted to either party hereunder or is to be implied under or against any patent of any third party and the parties hereto make no guarantees or representations concerning the patents of others or concerning the application or lack of application of any such patent to any operation which I.C.I. or GLAXO or Subsidiaries or Associates may conduct hereunder .....

(c) If at any time during the continuance of this Agreement either party shall become aware of any infringement or threatened infringement of any patent at any time the subject of this Agreement the party having knowledge thereof shall forthwith give notice thereof to the other and the parties shall thereupon consult together as to the action to be taken. If in such event the owner of the patent involved (I.C.I. or GLAXO as the case may be) shall not be

willing to take legal proceedings against any infringer, then subject to the written consent of the owner (which consent shall not be unreasonably withheld) the other party or a Subsidiary or Associate of it or any Independent Third Party licensed or sublicensed by GLAXO to make use and sell griseofulvin may at its own expense take such proceedings and in such case any damages recovered shall belong to it. For the purpose of such proceedings the owner aforesaid shall permit if such be legally necessary the use of the owner's name and shall execute such documents and do such acts as may be necessary and the owner shall be indemnified against all costs damages and expenses occasioned thereby and shall be kept informed of the progress of such proceedings by the aforesaid party Subsidiary Associate or Independent Third Party taking such proceedings .....

10. IMPROVEMENTS.

(a) If during the continuance of this Agreement GLAXO shall make discover or acquire in relation to the production of griseofulvin and preparations containing the same (or in relation to the use of any of the foregoing for the purposes of this Agreement) any invention whether patented or not or any process relating to or derived from or any improvement upon the Know-how GLAXO shall unless prevented by the terms of any such acquisition communicate the same to I.C.I. and thereby authorise I.C.I. its Subsidiaries and Associates to make use and sell griseofulvin and preparations containing the same thereunder and/or in accordance therewith during the continuance of and in accordance with this Agreement without payment additional to that provided in Clause 5 hereof PROVIDED ALWAYS that if such rights shall only have been acquired by GLAXO subject to payment GLAXO shall be entitled to request I.C.I. and I.C.I. shall if it shall desire to be entitled to such rights pay to GLAXO a fair proportion (which proportion shall be agreed between the parties hereto) .....

(b) If during the continuance of this Agreement I.C.I. shall make discover or acquire in relation to the production of griseofulvin and preparations containing the same (or in relation to the use of any of the foregoing for the purposes of this Agreement) any invention whether patented or not or any process relating to or derived from or any improvement upon the Know-how I.C.I. shall unless prevented by

the terms of any such acquisition communicate the same to GLAXO and thereby authorise GLAXO and its Subsidiaries (and subject to I.C.I.'s express consent any Independent Third Party licensed or sublicensed by GLAXO to make use and sell griseofulvin) to make use and sell griseofulvin and preparations containing the same thereunder and/or in accordance therewith during the continuance of and in accordance with this Agreement without payment additional to that provided in Clause 6 hereof PROVIDED ALWAYS that if such rights shall only have been acquired by I.C.I. subject to payment I.C.I. shall be entitled to request GLAXO and GLAXO shall if it shall desire to be entitled to such rights pay to I.C.I. a fair proportion (which proportion shall be agreed between the parties hereto) .....

(c) At least one year prior to the expiration of this Agreement (as provided for in Clause 7 hereof) GLAXO and I.C.I. shall consider together whether either party wishes to retain patent rights obtained hereunder beyond the life of this Agreement and if so on what terms they shall be permitted to do so .....

11. TRADE MARKS AND GET-UP.

The parties hereto mutually undertake not to use and not to permit any Subsidiaries or Associates to use on any product sold hereunder any trade mark name or designation likely to be confused with any trade mark name or designation used by the other party or Subsidiaries or Associates thereof and further undertake not to use knowingly or intentionally a get-up for any such product likely to be confused with those of the other party or Subsidiaries or Associates thereof unless otherwise agreed in writing by the parties hereto. GLAXO undertakes in any Agreements with Independent Third Parties granting licences and/or sublicences under patents the subject of this Agreement to endeavour to incorporate therein provisions similar to those contained in this clause and in furtherance of this and the provisions of this clause the parties hereto agree on request to provide information to the other on trade marks names designations and get-up with the right to pass on such information unless otherwise specified to Subsidiaries or Associates and licensees or sublicensees of patents the subject of this Agreement .....

12. TERMINATION.

(a) In the event that either party defaults or breaches any of the provisions of this Agreement other than by reason of Force Majeure the other party shall have the right to terminate this Agreement by giving sixty days written notice to the defaulting party provided however that in the case of a default or breach capable of being made good if the said defaulting party shall make good the said default or breach within sixty days after said notice shall have been given then the said notice shall not be effective .....

(b) If I.C.I. or GLAXO shall have a Receiver appointed of the whole or any part of its assets or if an order is made or a resolution passed for winding up I.C.I. or GLAXO unless such order or resolution is part of a scheme of reconstruction of I.C.I. or GLAXO this Agreement shall without further action or notice forthwith terminate .....

(c) The expiration or sooner termination of this Agreement shall be without prejudice to the obligation of I.C.I. to pay GLAXO all royalties accrued due and payable under Clause (a) hereof to the obligation of I.C.I. to preserve the secret and confidential nature of the Know-how and any information conveyed by GLAXO under the provisions of Clause 10(a) hereof for so long as it shall not be in the public domain and to any other right of or remedy available to GLAXO at such expiration or sooner termination .....

(d) The expiration or sooner termination of this Agreement shall be without prejudice to the obligation of GLAXO to remit or have remitted to I.C.I. all payments due and payable under Clause 6(a) hereof to the obligation of GLAXO to preserve the secret and confidential nature of any information conveyed by I.C.I. under the provisions of Clause 10(b) hereof for so long as it shall not be in the public domain and to any other right of or remedy available to I.C.I. at such expiration or sooner termination .....

13. WAIVER.

The failure on the part of either of the parties hereto to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right nor operate to bar the exercise or enforcement thereof at any time or times thereafter .....

14. NOTICES.

Any notice or consent required to be given by either party hereunder shall be given by registered letter addressed to the party for whom it is intended at the address set forth in the preamble to this Agreement or at such other address as such party may designate in writing. Any such notice or consent shall be deemed to have been given when it would have been delivered in the ordinary course of post .....

15. ARBITRATION.

Any dispute controversy or claim arising out of or relating to any of the provisions of this Agreement or the breach thereof shall be referred to an arbitrator to be agreed between the parties and in default of such agreement to be nominated by the President for the time being of the Law Society and such reference shall be deemed to be an arbitration agreement within the meaning of the Arbitration Act 1950 or any re-enactment or modification thereof for the time being in force .....

16. MUTUAL HELPFULNESS.

Whilst it is recognised that the provisions of this clause are of no legal effect whatever the parties hereto wish to record the spirit of this undertaking to be one of mutual helpfulness and in the event that this Agreement in any of its provisions is found unfair in practice either party shall feel free to make representation to the other for the mutual consideration of changes and if either party hereto shall make discover or acquire any invention relating to useful griseofulvin analogues or homologues or derivatives of the same or of griseofulvin itself which it shall be free to disclose to the other then the parties shall consider whether and on what terms (as to royalty territory and otherwise) they can together exploit such homologues analogues and derivatives to their mutual benefit .....

17. TITLES.

It is agreed that the marginal headings herein and the list of contents have been inserted for convenience only and do not constitute any part of this Agreement .....

IN WITNESS WHEREOF the hands of the authorised representatives of the parties hereto as of the day and year first above written .....

WITNESS to the signature of the
authorised representative of
GLAXO LABORATORIES LIMITED

GLAXO LABORATORIES LTD.
/s/ A. E. BIDE, *Secretary*
/s/ F. J. WILKINS, *Director*

WITNESS to the signature of the
authorised representative of
IMPERIAL CHEMICAL INDUSTRIES
LIMITED

IMPERIAL CHEMICAL
INDUSTRIES LTD.
/s/ D. S. LAPPIN
/s/ T. W. M. BLAND, *Director*
Pharmaceutical Division
Secretary

SCHEDULE A hereinbefore referred to:

Country	Serial or Application Number	Patent Number
United Kingdom		810377
		810378
Australia	31174/57	
	31180/57	
Brazil	97204	
	97205	
British Guiana		
Ceylon		
Federation of Malaya		
Ghana		
Hong Kong		
India	61705	
	61706	
Jamaica		
Kenya		
Mexico	48890	
	48892	
New Zealand	119595	
	119596	
Nigeria		
Northern Rhodesia		
Pakistan		108808
		108809
Singapore		
South Africa	2947/57	
	2948/57	
Tanganyika		
Uganda		
U.S.A.		2900304

SCHEDULE B hereinbefore referred to:

Country	Serial or Application Number	Patent Number
United Kingdom		784618
		788118
		791603
		795039
	11098/59	
	7197/59	
	11097/59	
	14338/59	
Argentina		105524
		108203
Australia		207867
		210823
		218417
	44872/59	
Brazil	85566	
	86530	
Canada		576638
		575390
	706845	
	720595	
Denmark		87152
	1033/56	
	1712/56	
Eire	160/56	
	257/56	
	355/56	
France	711573	
	717195	
		1167587
		1170792
Germany		1018588
		1021539
		1040187
		1044501
	G 23764 IVa/30h	
	G 26174 IVb/12qu	

Country	Serial or Application Number	Patent Number
Holland	205788	
	207148	
	213456	
	208228	
	236143	
India		56844
		57273
		57645
Israel		9428
		9560
		9625
Italy	96/422	
	98/260	
	5/395	
	99/408	
Japan	31-7765	
	12880/56	
	31-32730	
	31-16246	
New Zealand		116120
		116429
		116688
	122717	
Norway		93918
		93919
		91111
Pakistan		106848
		107560
		106851
South Africa		891/56
		1459/56
		1853/56
Sweden		164660
	4326/56	
	5870/56	

Country	Serial or Application Number	Patent Number
U. S. A.	582927	2843527
	631993	
	592270	
	662985	

SCHEDULE C hereinbefore referred to:

Assia Chemical Laboratories Limited

TEL AVIV

Israel.

APPENDIX C ANNEXED TO ICI NOV. 8, 1968, MEMORANDUM OF POINTS AND AUTHORITIES—ICI-AMHO AGREEMENT OF SEPT. 12, 1958

IMPERIAL CHEMICAL INDUSTRIES LIMITED
PHARMACEUTICALS DIVISION
FULSHAW HALL, WILMSLOW, CHESHIRE

12th September, 1958.

American Home Products Corp.,
22, East 40th Street,
New York, 16,
U. S. A.

Dear Sirs,

Following discussions which have taken place between our two companies, it is agreed:—

(1) You are appointed as the sole importer, processor and distributor of such of our pharmaceutical products for human and veterinary use as may be agreed from time to time in the United States of America, Hawaii, Alaska and Puerto Rico and in such other territories as may be agreed between us from time to time. It is understood that this appointment may be extended to such of your subsidiary companies as may be agreed between us from time to time.

(2) This appointment shall remain in force until 31st December 1965 and we will review with you not later than 31st December 1960 whether or not it should be further extended to the end of 1970.

(3) In addition to those of our products which you already handle we will offer you for sale in your territory any new product that we may develop and that we consider appropriate for sale in your territory, subject to its being agreed between us that such a product can suitably be handled by yourselves having regard to all the circumstances surrounding that product. It is understood that, once such an offer is made, you will advise us within a reasonable period of time if you intend, or not, to market the product concerned.

(4) Should it be agreed between us for any reason that you will not handle one of our products, we shall

forthwith be at liberty to offer such a product to any other firm in your territory.

(5) Once it is agreed that you shall be responsible for any of our products, your rights under Clause (1) in its sale in your territory will continue during the period of your appointment as our sole importer, processor and distributor except that either party shall always be at liberty, on giving reasonable notice, to withdraw any product from this arrangement if either party is dissatisfied as to its quality or profitability or if either party is of the opinion that it has become obsolete.

(6) Should your appointment as our sole importer, processor and distributor terminate, we shall have the right to sell directly or through some third party in your territory any of our products notwithstanding any continuing rights you may have to handle such a product. Provided that your appointment is not terminated by I.C.I. under Clauses (13) or (14) we will on such termination:—

(i) grant to you a non-exclusive licence in your territory at a royalty to be agreed under any relevant patents to make, have made, use and sell such products as were the subject of this appointment immediately prior to termination and

(ii) be willing to supply your requirements of any of those products for your territory at prices and on conditions to be agreed for a period of five years from the termination of your appointment or for the period until we cease to manufacture that product or products whichever shall be the shorter.

(7) (i) We will assign to A.H.P. for the period of their appointment our U.S. trade marks for the products which fall within the scope of this appointment. Should A.H.P.'s appointment terminate, their rights in any trade marks assigned to them under this appointment will continue unless,

(a) A.H.P. themselves terminate the agreement for any reason except those envisaged in Clause (13) below, or

(b) I.C.I. terminate the agreement under Clauses (13) or (14), below,

In either of which cases A.H.P. will before the termination of the agreement executed an assignment which shall become operative on the day when the agreement terminates, re-assigning to us all our trade marks that have been assigned to them together with the good will attached to and symbolised by such trade marks.

(ii) A.H.P. shall in any case re-assign to I.C.I. any trade mark assigned to A.H.P. by I.C.I. by virtue of this Agreement together with the good will attached to and symbolised by the said trade mark if at any time (whether during the currency of this Agreement or afterwards) A.H.P. shall cease to use that trade mark.

(iii) During the currency of the agreement, A.H.P. will take such action as is necessary to maintain the trade marks assigned to them by us and their registrations valid and effective.

(iv) During the currency of the agreement A.H.P. will not, without our prior consent, use or register any trade marks assigned to them by us on or for any products which do not fall within the scope of this appointment nor will they register or use any trade marks confusingly similar to such trade marks for goods within the scope of this agreement or for any substitutes therefor or for similar goods.

(8) It is understood that circumstances may arise in which it is preferable for you to obtain your supplies of the products from other manufacturing sources and we will allow you to make such purchases in cases where I.C.I. agrees that it would be in our mutual interest.

(9) It is recognised that it will be to our mutual advantage to co-operate, from the earliest practicable stage, in the exchange of formulation, therapeutic processing and packing knowledge relating to our products which it is proposed should eventually be processed and packed in your territory and it is therefore agreed that we shall disclose to you, in confidence, details of such knowledge acquired by us in the development of such products and specific to such products and that you will similarly disclose to us such knowledge acquired by you in the development of these products for sale in your territory.

(10) You will use your best endeavours (no less than those used in respect of the promotion of your other products consistent with market potential) to promote business in the products concerned.

(11) In order to secure the most rapid development and use in your territory of new discoveries, requiring F.D.A. approval for sale, you will co-operate fully with us in the promotion and progressing of clinical trials which it is mutually agreed should be established in the U.S.A. It is recognised that the respective responsibilities, terms and other conditions for the establishment of such trials will require separate discussion and agreement in each case as it arises.

(12) The conditions to be applied to our sales to you of the products concerned shall be agreed between us from time to time. Any such agreement will be in the form of a letter, each product to be the subject of a separate letter which will at the same time cover any other details not already provided for by the present letter, including rates of royalty which may arise, any particular labelling requirements and any warranties concerning patents and trade marks, as may be appropriate. As soon as possible after your acceptance of this letter we will agree on the future terms and conditions applicable to our sales to you of our products that you at present handle.

(13) Either of us shall be at liberty to terminate your appointment as sole importer, processor and distributor if the other withholds for more than two months after notice monies due that are not in dispute or commits or permits any substantial breach of the terms of this arrangement. Each of us will give notice to the other of any such withholding or breach and the other will have two months after receipt of the notice within which to correct such withholding or breach.

(14) This arrangement is personal to the two parties and shall not be assigned by either of them without the consent of the other. The arrangement shall also be terminable forthwith by either party in the event of any substantial change in the ownership or control of the pharmaceutical business of the other party.

If you agree to the above, we should be grateful if you

would sign both copies of this letter in the space provided below and return one copy to us.

Yours faithfully,
Imperial Chemical Industries Limited
Pharmaceuticals Division
E. D. CAREY,
Managing Director.

Agreed on behalf of American Home Products Corporation.

Signed

Date Dec. 17, 1958

EXHIBIT 4, ANNEXED TO WALLACE AFFT. OF OCT. 31, 1968—ICI-AMHO AGREEMENT OF DEC. 19, 1962

IMPERIAL CHEMICAL INDUSTRIES LIMITED
PHARMACEUTICALS DIVISION
FULSHAW HALL, WILMSLOW, CHESHIRE

4th October, 1962.

American Home Products Corporation,
22, East 40th Street,
New York, 16,
New York, U.S.A.

Dears Sirs,

GRISEOFULVIN

We refer to our letter of 12th September, 1958, appointing you our sole importer, processor and distributor of certain of our pharmaceutical products for human and veterinary purposes in the United States of America, Hawaii and Puerto Rico (which in this letter we shall refer to as the United States). We are now writing to offer you our product griseofulvin for sale in the United States subject to the general conditions outlined in our letter of 12th September, 1958 (or any extension thereof) and subject also to the following conditions:—

1) You will place firm orders with us from time to time for griseofulvin in bulk containers and we shall execute such orders to the best of our ability, subject to our not being prevented for any reason of force majeure, and having regard to your commitments in the United States, to the quantities available from time to time, the requirements of other customers and the productive capacity of our plant. Title to all goods ordered shall pass to you on being placed aboard a steamer or other carrier at a British port. Your orders will be for the goods f.o.b. United Kingdom port and terms of payment will be net 90 days from the date of issue of the invoice.

2) The price we shall apply to sales of griseofulvin in bulk containers will be $78.40 per kilo f.o.b. U.K. or such other price as shall be agreed in writing between us from time to time.

3) The cost of publicity will be borne by you and we shall supply you with any information and data which you may reasonably require for use in the preparation of printed matter and publicity material.

4) You will supply us from time to time with reports of your progress in selling griseofulvin and the state of the market as it affects your sales.

5) You will label griseofulvin in accordance with our colour scheme and each label will indicate clearly that the product is distributed in the U.S.A. by arrangement with Imperial Chemical Industries Limited.

6) You will at all times strictly adhere to the formulae and methods developed or approved by us in manufacturing, processing and repacking griseofulvin and will not employ formulae and methods not first approved of by us.

7) You will not, without first obtaining our consent, resell or re-deliver in bulk supplies of griseofulvin.

8) The rights granted to you by this letter do not include rights to sell griseofulvin to customers outside the United States or to sell it to customers within the United States for export from the United States. You may, however, sell griseofulvin to the U.S. Government for use by that Government outside the United States.

9) You will give no warranty or guarantee in connection with griseofulvin unless this has been authorised by us in writing.

10) We will grant you a non-exclusive license or sublicence under any relevant United States patents of ourselves and/or Glaxo Laboratories Limited of Greenford, Middlesex, England, to manufacture, process, re-pack and sell dosage forms of griseofulvin from griseofulvin supplied to you by us in bulk under Paragraph (1) above.

11) a) You will pay us at our offices at Fulshaw Hall, Wilmslow, England, in U.S. dollars a royalty equal to 5% or such other percentage as may be agreed in writing between us from time to time of the aggregate net invoiced sales value of griseofulvin sold by you. The agreed royalty is payable by you in consideration of the patent rights granted to you under paragraph (10) above and of Clause 9 of the letter of appointment dated 12th September, 1958; unless the grant to you of those patent rights is earlier withdrawn such a royalty payment shall remain in effect

either for the duration of your appointment under the letter dated 12th September 1958 (or any extension thereof) or until the expiry of the last to expire of the United States patents referred to in paragraph (10) above whichever is the longer period. The term "aggregate net invoiced sales value" shall mean the sum of the sales prices invoiced in the period less:

i) returns and allowances,
ii) cash and trade discounts,
iii) delivery charges pre-paid or allowed to customers,
iv) excise or other taxes assessed against the manufacture use or sale of the products.

b) Payment of royalty shall be made quarterly within 90 days of the end of each calendar quarter and shall be in respect of all sales of griseofulvin made by you during the previous calendar quarter. Within 60 days of the end of each such calendar quarter you shall send to us a statement showing the aggregate net invoiced sales value of all griseofulvin so sold by you during the said previous calendar quarter.

If you agree to the above, we should be grateful if you would sign both copies of this letter in the space provided below and return one copy to us.

Yours faithfully,

IMPERIAL CHEMICAL INDUSTRIES LIMITED
PHARMACEUTICALS DIVISION,

T.W.M. Bland, *Division Secretary*

Agreed on behalf of American Home Products Corporation:

Signed [illegible] Date 12/19/62

AFFIDAVIT BY PAUL N. KOKULIS, DATED NOV. 7, 1968

Paul N. Kokulis, being duly sworn, deposes and says the following:

(1) That I am a partner in the firm of Cushman, Darby & Cushman, 730-15th Street, N.W., Washington, D.C., patent counsel for Imperial Chemical Industries Limited (ICI);

(2) That upon instructions from ICI, I have asked the Commissioner of Patents to publish notice of the availability of U.S. Patent 2,900,304, issued August 18, 1959, entitled "GRISEOFULVIN USES AND COMPOSITIONS," assigned to ICI, for license at reasonable terms and conditions in accord with the usual practice for making patents available;

(3) That a copy of my letter to the Commissioner of Patents pursuant to (2) above is attached hereto as Exhibit A.

EXHIBIT A, ANNEXED TO KOKULIS AFFT. OF NOV. 7, 1968

CUSHMAN, DARBY & CUSHMAN
ATTORNEYS AT LAW
AMERICAN SECURITY BUILDING
730 Fifteenth Street, N.W.
Washington, D.C. 20005

November
Seven
1968

Hon. Commissioner of Patents
Washington, D.C.

Subject: Publication of Notice of Patent Available for Licensing

Sir:

Imperial Chemical Industries Limited, the assignee of the entire right, title and interest in U.S. Patent 2,900,304, issued August 18, 1959 and entitled "GRISEOFULVIN USES AND COMPOSITIONS," is prepared to grant non-exclusive licenses under said patent at reasonable terms

and conditions. Accordingly, it is requested that appropriate notice of the availability of this patent for license be published in the Official Gazette. The following notice is proposed:

> "Imperial Chemical Industries Limited is prepared to grant non-exclusive licenses under U.S. Patent 2,900,304, issued August 18, 1959 and entitled "GRISEOFULVIN USES AND COMPOSITIONS" at reasonable terms and conditions. Request for license under the patent may be addressed to: The Patent Agent, Imperial Chemical Industries Limited, Thames House North, Millbank, London S.W. 1, England."

The required fee is attached hereto.

Respectfully submitted,
CUSHMAN, DARBY & CUSHMAN

AFFIDAVIT OF THOMAS WALTER MEREDITH BLAND, DATED NOVEMBER 29, 1968, ANNEXED AS APPENDIX II TO REPLY MEMORANDUM OF DEFENDANT ICI IN SUPPORT OF ITS CROSS-MOTION FOR SUMMARY JUDGMENT AGAINST PLAINTIFF ON GROUNDS OF MOOTNESS AND FAILURE TO ESTABLISH VIOLATION OF THE SHERMAN ACT, FILED DECEMBER 3, 1968

[Caption Omitted]

I, THOMAS WALTER MEREDITH BLAND, being duly sworn, depose and state that:—

(1) I am, and for the past twenty-two years have been, the Secretary of the Pharmaceuticals Division of Imperial Chemical Industries Limited (hereinafter described as "ICI"), the offices of which Division are located in Macclesfield, Cheshire, England. In my capacity as Secretary of said Division, I exercise general supervision over the documents and files of the Division, and am familiar with the agreements, memoranda and other documents of the Division and with the activities of the officials and employees of the Division.

(2) During the period since the completion of the Distributorship Agreement on Griseofulvin with American Home Products Corporation (hereinafter described as "AMHO") until the Clause relating to the resale of Bulk Form Griseofulvin was removed, no approaches were made to ICI by companies (other than AMHO) in the United States expressing an interest in purchasing, enquiring as to the availability of, or requesting Bulk Form Griseofulvin other than those which have been given in the answers to Interrogatory No. 67. From an examination of those approaches it is apparent that, apart from a request from Unimed (which was for a small quantity for research purposes), there was no refusal by ICI to supply Griseofulvin in bulk for processing or resale in the United States.

(3) For convenience I summarize below and comment upon the approaches which were made during the period in question and are listed in answers to Interrogatory No. 67:

(a) *International Chemical Corporation* (1963)

This was a request for a quotation for Bulk Form

Griseofulvin to be supplied to customers in South America. The enquiry was addressed to ICI (New York) Inc. who referred it to ICI. ICI possess exclusive distributors in South America and were therefore themselves unable to supply. Accordingly the request was refused.

(b) *U.S. Summit Corporation* (1963)

This was a request for a quotation for Griseofulvin to be supplied to Japan. The approach was made to AMHO who referred it to ICI. ICI had an exclusive distributor in Japan and were therefore unable to make the sale and refused the request.

(c) *McKesson Robbins* (1963)

This was a request for Griseofulvin to be supplied to Colombia. The request was made to AMHO who suggested that the customer should approach ICI but ICI heard nothing further.

(d) *Unimed* (1964)

This was a request for a small consignment of Bulk Griseofulvin not to be used in commerce but for research purposes. The request was made to ICI (New York) Inc. who referred it to ICI. The request was refused.

(e) *Philipp Bauar* (1964)

This was a request for Griseofulvin to be supplied in Europe, the Far East and Mexico. The approach was made to ICI (New York) Inc. who referred it to ICI. ICI already possessed exclusive distributors in each of these countries and were therefore unable to make the sales and refused the request.

(f) *American Cyanamid Company* (1965)

This was a request to Glaxo for supplies of Bulk Griseofulvin for use in a topical formulation that American Cyanamid was developing. As far as ICI knows Glaxo made supplies available for development purposes but it seems that no commercial exploitation has taken place.

(g) *Nurani Farma* (1965)

This was an enquiry for Griseofulvin to be supplied

AFFIDAVIT OF ROBERT MAZON, DATED MAY 27, 1970

1. I am Vice-President for Manufacturing of Zenith Laboratories, Inc. ("Zenith"), a manufacturer of pharmaceutical products located in Northvale, New Jersey. I make this affidavit at the request of the United States Department of Justice for its use in a suit by it against Glaxo Group Limited ("Glaxo") and Imperial Chemical Industries Limited ("ICI"), which is pending in the United States District Court for the District of Columbia.

2. I have been in the pharmaceutical business for more than 20 years, 17 years of which in various capacities with American Cyanamid Company and the last 3 years with Zenith. I have personal knowledge of the matters set forth herein, and personally participate on a daily basis in the management of the business of Zenith.

3. Zenith is the leading generic manufacturer of pharmaceutical products in the United States. It operates from a modern specially constructed drug facility, and produces and markets products of the highest quality subject to the same standards of the U. S. Food & Drug Administration as the larger brand name companies, such as the Ayerst Laboratories Division of American Home Products Corp. Zenith depends on its ability to offer quality pharmaceutical products at the lowest possible price in competing with such brand name companies.

4. Zenith manufacturers the principal antibiotic products presently sold in the United States, including tetracycline, oxytetracycline, penicillins, ampicillin and chloramphenicol. With respect to each of these products, Zenith purchases the bulk raw material from others and performs the function in its plant of encapsulating or tableting, bottling and packaging this raw material into finished pharmaceutical products.

5. Zenith presently purchases the antibiotic griseofulvin microsize in finished capsules from American Home Products Corp., Ayerst Laboratories Division ("Ayerst") pursuant to Ayerst's letter dated March 31, 1969, a copy of which is attached hereto as Exhibit "A."

6. Zenith also has a license agreement dated January 23, 1969 with ICI to manufacture and sell bulk griseofulvin

(not microsize) under ICI's U. S. Patent No. 2,900,304, a copy of which agreement is attached hereto as Exhibit "B." Ayerst is ICI's sole distributor for this product in the United States (Exhibit "C"), and Ayerst has offered it to Zenith (Exhibit "A").

7. Glaxo has refused to sell Zenith bulk griseofulvin in microsize form or to license Zenith under its U. S. Patent No. 3,330,727 covering this product. A copy of Zenith's letter dated March 12, 1969, and Glaxo's response dated April 17, 1969 denying a license on this product are attached hereto as Exhibits "D" and "E."

8. I have repeatedly asked Ayerst about obtaining a supply of bulk griseofulvin in microsize form but to no avail, although Zenith obtains the griseofulvin microsize capsules from Ayerst. Since our business is encapsulating or tableting, bottling and packaging pharmaceuticals, we cannot make a sufficient mark-up on the sale of Ayerst's griseofulvin capsules to make them a profitable item, and we have sold very few of these capsules.

9. With respect to the bulk griseofulvin not in microsize form covered by Zenith's license with ICI, there is not a sufficient market for this product in the United States to warrant our offering the item.

10. With respect to ICI's license to Zenith to manufacture its own bulk griseofulvin, Zenith is not in the business of manufacturing bulk chemicals, and therefore such a license to Zenith is useless.

11. In order to compete effectively with the brand name companies like Ayerst, Zenith must be able to offer its products at a lower price. However, Zenith must pay Ayerst $25.15 per 100 capsules (125 mg.), and yet compete with Ayerst. Zenith's price thus results in few sales, and Zenith manufacturing facilities for griseofulvin capsules are unused.

12. Zenith believes that it is at a great disadvantage competitively in not being able to purchase bulk griseofulvin in microsize and to manufacture and market these capsules in the United States. If this product were available to Zenith, we believe that Zenith could make substantial sales of the griseofulvin microsize capsules that it would manufacture at a reasonable profit.

/s/ ROBERT MAZON

EXHIBIT A, ANNEXED TO MAZON AFFIDAVIT OF MAY 27, 1970

AYERST LABORATORIES
DIVISION OF AMERICAN HOME PRODUCTS CORPORATION
685 Third Avenue, New York, N.Y. 10017

[notation on letter] RM
Called Ayerst 4-10-69—Mr. Davis was out of town left message with his secretary that you are interested in this quote and would follow through as soon as you return from Italy.

March 31, 1969

Mr. Robert Mazon
Vice President
Zenith Laboratories, Inc.
150 South Dean Street
Englewood, New Jersey

Dear Mr. Mazon:

We received on March 20 your letter dated March 7, which was mailed on March 19.

In the meantime, we have been examining our capabilities of supplying you with the amounts of bulk griseofulvin and microsize capsules you requested. Since we have several other pending commitments and a limited capacity, our ability to supply you is contingent upon the availability of raw material from our supplier. Therefore, the prices quoted below are subject to withdrawal at any time without prejudice to us.

BULK GRISEOFULVIN

Quantities of 50 kilos—$123.00 per kilo
100 kilos—$120.00 per kilo
250 kilos—$117.00 per kilo

All prices are f.o.b. Rouses Point, New York, and the terms are net 10 days. It should also be specified that the quantity discount is applicable only when one shipment is made.

So that you may have the material you requested to conduct your clinical study, we would be able to supply you with quantities smaller than 50 kilos at the 50 kilo price.

Also, listed below are the prices for griseofulvin microsize capsules.

GRISEOFULVIN MICROSIZE CAPSULES

125 mg. potency at $25.15 per 1000 capsules
250 mg. potency at $46.30 per 1000 capsules

The minimum quantity order is 500,000 capsules of each potency, prices quoted are f.o.b. Rouses Point, New York, terms are net 10 days following the date of the invoice.

Orders for any form of griseofulvin must be submitted to us at least 90 days prior to date of expected shipment. When your order is shipped you will receive the necessary certification documents.

Very truly yours,

William L. Davis

EXHIBIT C, ANNEXED TO MAZON AFFIDAVIT OF MAY 27, 1970

IMPERIAL CHEMICAL INDUSTRIES LIMITED
PHARMACEUTICALS DIVISION
ALDERLEY HOUSE, ALDERLEY PARK, MACCLESFIELD, CHESHIRE

Mr. Robert Mazon, Vice President,
Zenith Laboratories Inc.,
150, South Dean Street,
Englewood,
New Jersey 07631,
U.S.A.

15th January 1969.

Dear Mr. Mazon,

Griseofulvin—U.S. Patent 2,900,304

Thank you for your letter of 18th December 1968. I enclose two copies of a draft license agreement. If you have any comments on this you will no doubt let me know. On the other hand, if the form is acceptable to you, you could execute the two copies and return them to me and I would let you have back one copy executed by ICI.

I should perhaps add that as we have appointed the Ayerst Laboratories Division of American Home Products Corporation sole importers and distributors of our griseofulvin in the U.S.A. we should not be in a position to supply you direct. If, therefore, you do not propose yourselves to undertake manufacture, you will have to obtain your supplies either from Ayerst or some other supplier.

Yours truly,

T.W.M. BLAND,
Division Secretary.

EXHIBIT D, ANNEXED TO MAZON
AFFIDAVIT OF MAY 27, 1970

March 12, 1969

Glaxo Laboratories Limited
Greeenford, Middlesex,
England

Gentlemen:

We are interested in marketing Griseofulvin in the United States and accordingly would request a license under your Patent No. 3,330,727 relating to a Griseofulvin having a high specific surface area.

We are presently licensed by Imperial Chemical Industries Limited under their Griseofulvin U.S. Patent No. 2,900,304.

Your prompt attention to our request would be most appreciated. Thank you.

Very truly yours,

ZENITH LABORATORIES, INC.
ROBERT MAZON
Vice President

EXHIBIT E, ANNEXED TO MAZON AFFIDAVIT OF MAY 27, 1970

GLAXO GROUP LIMITED
CLARGES HOUSE, 6-12 CLARGES STREET, LONDON, W1Y 7PH

Mr. Robert Mazon,
Vice President,
Zenith Laboratories Inc.
150 South Dean Street,
Englewood,
New Jersey 07631,
U.S.A.

17th April, 1969.

Dear Mr. Mazon,

I regret the delay in replying to your letter of March 12th concerning your request for a licence under USP 3,330,727.

After careful consideration of the commercial aspects of our existing arrangements for the distribution of griseofulvin in the U.S.A. we are satisfied that these are entirely satisfactory. Therefore, with regret, I have to inform you that we do not consider it to be in our commercial interests to grant you a licence at the present time.

Yours truly,

GLAXO GROUP LIMITED
H. W. MARTIN,
Manager, Industrial Property & Contracts Dept.

AFFIDAVIT OF EUGENE C. DOONER, JR., DATED JUNE 5, 1970.

[Caption Omitted]

1. I am the President of Dooner Laboratories, Inc., Ward Hill, Haverhill, Massachusetts. I have been in the pharmaceutical business for about 22 years. I began as a salesman in 1949 for McNeil Laboratories, Inc., a subsidiary of Johnson & Johnson and became McNeil's Government Sales Representative in 1949; after which I was appointed its Field Hospital Manager in 1961; its Hospital Sales Manager in 1963; and its Director of Hospital Sales in 1965. I left McNeil in August 1967 to establish Dooner Laboratories, Inc.

2. Dooner Laboratories, Inc. is a small pharmaceutical firm incorporated under the laws of Massachusetts in August 1967. The firm occupies a new modern building of 15,000 square feet on three and one-half acres of land at the above address in Haverhill, Massachusetts. The firm is engaged in the development, and distribution of pharmaceuticals. The firm purchases some of its products in finished dosage form. These products are received from contract manufacturers in bulk containers and repackaged into trade packages for distribution and sale. We have completely new and modern packaging facilities for capsules, tablets and liquids. Our quality control laboratories are neat, spacious, and contain the latest analytical equipment. Dooner Laboratories, Inc., meets Food and Drug Administration inspection requirements and operates within the required guidelines of this agency.

3. Our company's products are sold through its own sales force of nine salesmen, six of whom devote their full time to sales. The company's salesmen call on doctors, pharmacists, hospitals and other health-care institutions in their territories, to promote the company's products. The company also relies heavily on direct mailings of samples and literature to doctors and hospitals, and displays its products at medical conventions. The company markets its products through drug wholesalers who in turn sell the products to retail drugstores and hospitals. Our marketing and sales personnel possess the background and experience required to market pharmaceutical products.

4. The following exhibits attached to this affidavit are true copies of letters received or prepared by me in the carrying out of our company's business. They have been retained in the company's files until I caused them to be taken from the files in order to make the attached xerox copies. Such letters were prepared by or received by me on or about the dates indicated thereon.

Exhibit	Date	Sender	Recipient
1	June 9, 1968	Dooner	Temple, Glaxo
2	July 30, 1968	Martin, Glaxo	Dooner
3	Aug. 6, 1968	Dooner	Martin, Glaxo
4	Sept. 6, 1968	Dooner	Martin, Glaxo
5	Sept. 16, 1968	Dooner	Martin, Glaxo
6	Oct. 2, 1968	Dooner	Martin, Glaxo
7	Dec. 19, 1968	Martin, Glaxo	Dooner
8	Dec. 31, 1968	Dooner	Martin, Glaxo
9	Feb. 13, 1969	Martin, Glaxo	Dooner
10	May 4, 1970	Dooner	Glaxo
11	June 27, 1968	Dooner	McNey, McNeil
12	July 10, 1968	McNey	Dooner
13	June 27, 1968	Dooner	Longman, Schering
14	July 3, 1968	Longman, Schering	Dooner
15	June 28, 1968	Dooner	Johnson, Ayerst
16	July 19, 1968	Johnson, Ayerst	Dooner
17	Aug. 8, 1968	Dooner	Johnson, Ayerst
18	Sept. 4, 1968	Davis, Ayerst	Dooner
19	Sept. 25, 1968	Hockney, ICI	Dooner
20	Nov. 25, 1968	Dooner	Patent Agent, ICI
21	Dec. 10, 1968	Bland, ICI	Dooner
22	Dec. 20, 1968	Dooner	ICI
23	Jan. 15, 1969	Bland, ICI	Dooner
24a-b	Draft License Agreement Between ICI and Dooner, undated, 2 pp.; Dooner's additions on p. 2.		
25	Jan. 23, 1969	Dooner	Bland, ICI
26	Feb. 13, 1969	Bland, ICI	Dooner
27	May 4, 1970	Dooner	ICI
28	Mar. 14, 1969	Ankerfarm	Dooner
29	Mar. 25, 1969	Dooner	Ankerfarm
30	Apr.2, 1969	Ankerfarm	Dooner
31	Nov. 5, 1968	Shibata, Nippon	Dooner

Exhibit	Date	Sender	Recipient
32	Nov. 26, 1968	Dooner	Shibata, Nippon
33	Dec. 12, 1968	Nippon	Dooner
34	Dec. 20, 1968	Dooner	Nippon
35	Jan. 7, 1969	Shibata, Nippon	Dooner
36	Jan. 13, 1969	Kaede, Koyo	Dooner
37	Jan. 16, 1969	Dooner	Shibata
38	Jan. 30, 1969	Nippon	Dooner
39	Feb. 5, 1969	Dooner	Nippon
40	Feb. 21, 1969	Nippon	Dooner
41	Feb. 28, 1969	Dooner	Nippon
42	Mar. 12, 1969	Nippon	Dooner

5. In about 1960, while I was employed by McNeil Laboratories as a salesman, I learned that McNeil planned to market griseofulvin in the United States. My principle sales experience with griseofulvin was in the institutional market, where I was responsible for selling McNeil's griseofulvin product ("Grifulvin") to city, county, and state institutions, private hospitals, and federal institutions. I found that the product had a large market potential and it generated great interest in the medical community. I remained very active in the sale of griseofulvin until the time I left McNeil in 1967 to establish my own firm.

6. After I had started my own company, I read in the trade press about the government's suit against Glaxo and ICI, in early 1968, relating to griseofulvin. Because of my background in selling the drug and my knowledge of the potential market for it, I became interested in the possibilities of selling it on behalf of my company. Although while at McNeil I had known that the company enjoyed some exclusivity in the sale of the product, I thought that the lawsuit might make it possible for additional parties to acquire the drug for sale in this country.

7. I therefore first wrote to Mr. Temple, the Export Sales Manager of Glaxo, on June 9, 1968, requesting a licensing arrangement for the marketing of griseofulvin in the United States (Exhibit 1). After an exchange of several additional letters (Exhibits 2-6), Mr. Martin of Glaxo wrote to me, on December 19, 1968, that his company was convinced that its existing distribution arrangements in the United States were entirely satisfactory and that there-

fore he had to inform me that Glaxo would not wish to enter into supply transactions of bulk griseofulvin with me (Exhibit 7). I subsequently wrote Glaxo twice again, but have not received any favorable reply (Exhibits 8-10).

8. My second attempt to buy griseofulvin in bulk began with my writing a letter to Mr. McNey, president of McNeil, on June 27, 1968 (Exhibit 11). I asked that McNeil quote prices and terms to me respecting both micro and regular size griseofulvin. On July 10, 1968, Mr. McNey replied that McNeil was not interested in selling the product to me (Exhibit 12). At the same time, I wrote a similar letter to Dr. Longman, vice president and general manager of Schering Corp. (Exhibit 13). Dr. Longman's response was that his company was not in a position to quote prices to me on the item (Exhibit 14).

9. The fourth company I contacted was Ayerst Division of American Home Products Corp., on June 28, 1968 (Exhibit 15). After a further exchange of correspondence (Exhibits 16-17), Ayerst quoted me a price of $118 per kilogram of the bulk drug, in the regular form of griseofulvin (Exhibit 18). I intended to sell griseofulvin only in the micro-size form, because I did not believe that the regular size griseofulvin would continue to be as marketable a product. Thus because the $118 per kilogram cost of buying the regular size griseofulvin to which is added the cost of micronizing regular size griseofulvin, was so prohibitively high, I did not believe that I could market the drug competitively with the existing firms (Ayerst, Schering, McNeil.) (It is my understanding that the cost of micronized griseofulvin to these companies is approximately $60 per kilo.)

10. My fifth attempt to get griseofulvin was from Imperial Chemical Industries in the United States. I contacted one of their representatives by telephone and was advised that he could not deal with me. Shortly after that I received a letter from Mr. Hockney, the American manager for Imperial Chemical Industries Limited, dated September 25, 1968 (Exhibit 19). Mr. Hockney said that his colleagues in ICI American Inc. had told him of my approach to them with regard to supplies of griseofulvin in bulk. He advised me that ICI distributed the product in the United States only through Ayerst Laboratories, which had sole distributor rights. I then was given to understand, from reports

in the press, that ICI had filed a statement in the Patent Office and an affidavit in this case that it would be willing to license additional companies in the United States to sell griseofulvin, and I therefore wrote them again (Exhibit 20). On December 10, 1968, Mr. Bland of ICI replied (Exhibit 21) that they were willing to grant me a license under the patent, at a five per cent royalty rate, and sent me a draft agreement (Exhibit 24 a-b). On January 23, 1969, (Exhibit 25) I proposed three additions to the ICI draft licensing agreement (Exhibit 24b); providing protection against patent litigation, a reliable price list, and a right to purchase at a nondiscriminatory price, so that I would not be paying a higher price than my competitors paid to ICI. The reply, February 13, 1969, was negative and ICI indicated that it would sell to me only through Ayerst, if at all, and that I could not be guaranteed a nondiscriminatory or firm price (Exhibit 26). I again wrote to ICI, on May 4, 1970, requesting that they sell the chemical to me at the same price as they would to other accounts in the United States (Exhibit 27), but I have received no reply, and I am still unable to purchase griseofulvin from ICI on the same basis as the established firms.

11. I also tried to buy griseofulvin from two foreign companies, Ankerfarm S.P.A. of Milan and Nippon Kayaku Co. of Tokyo. Unfortunately, I discovered Ankerfarm did not have F.D.A. certification. (See Exhibits 28-30). Since the F.D.A. required that plants manufacturing antibiotics be certified, I could not legally market Ankerfarm's griseofulvin in the United States.

12. My experience with the Japanese firm was similar. They replied to my first letter negatively, because of risk of patent litigation, by letter of November 5, 1968 (Exhibit 31). In my next letter of November 26, 1968, I offered indemnification from patent liability, if they would sell to me (Exhibit 32). After a further exchange of correspondence (Exhibits 33-37) they offered to sell to me, but it turned out that their facilities for manufacturing the antibiotic were not certified by the United States F.D.A. I offered to pay the expense of F.D.A. certification, but they declined to accept this proposal (Exhibits 39-42).

13. I am still interested in acquiring griseofulvin for the purpose of selling it in the United States. As I pointed out in one of my letters to Glaxo (Exhibit 8) above, I be-

lieve that an additional supplier of this drug in the United States would expand the market. In addition, with added competition, price reductions might well be evident. The established marketers of this product in the United States may believe that they have saturated the market, but I do not believe that this is so. I believe that effective, competitively priced marketing of this drug would expand the total United States market for it; and I am still extremely interested in doing this, if I can secure the drug at a reasonable price.

14. It is necessary for me to secure the drug at a reasonable price, because I am not in a position to manufacture griseofulvin for my own use, by the fermentation process used to make the bulk drug. My company and I do not have the financial resources necessary to set up a fermentation plant for an antibiotic. I think that the cost of a small scale fermentation plant for a product of this type would run from half a million dollars to a million dollars, and I cannot afford to commit that kind of capital outlay. In addition, I am not an organic chemist, and would have to hire technical personnel to run such an operation.

15. Therefore, I can market griseofulvin effectively and competitively if I can buy it in bulk at a reasonable and nondiscriminatory price, so that I am on the same basis as my competitors who are doing the same thing (Ayerst, McNeil, Schering); I cannot market the product effectively unless I can buy the product in bulk form on equal terms as indicated. But I have been unsuccessful in securing a fair and legal source of bulk griseofulvin, despite diligent efforts to date.

16. Unless bulk griseofulvin becomes available to my company on a reasonable basis, without discrimination in terms, I do not believe that my company will be able to enter the business to offer the public the benefits of our competition and, in particular, the price reductions that might well take place.

/s/ Eugene C. Dooner, Jr.

EXHIBIT 1, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

June 9, 1968

Mr. M. R. Temple,
Export Sales Manager
Glaxo Limited
47 Park Street
London W. 1
England

Dear Mr. Temple:

Our company is interested in obtaining a licensing agreement with Glaxo Limited for the marketing of Griseofulvin in the United States.

Dooner Laboratories, Inc. is a new firm and within a matter of weeks will occupy one of the most modern pharmaceutical plants in New England.

We are anxious to hear from you and can assure you that your product will be marketed with the proper dignity of an ethical pharmaceutical.

Yours very truly,

DOONER LABORATORIES, INC.
EUGENE C. DOONER, JR.
President

EXHIBIT 2, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

GLAXO GROUP LIMITED
CLARGES HOUSE, 6-12 CLARGES STREET, LONDON, W.1

Mr. Eugene C. Dooner Jr.,
President,
Dooner Laboratories Inc.
P.O. Box 909,
Haverhill,
Massachusetts 01830,
U.S.A.

30th July, 1968.

Dear Mr. Dooner,

I have received your letter of 9th June addressed to Mr. M. R. Temple, asking for a licence to market Griseofulvin.

The whole matter of our Griseofulvin rights and licences thereunder are under review, and we will be glad to revert to the subject when the situation is clarified.

Yours sincerely,

H. W. MARTIN,
Industrial Property & Contracts Manager.

EXHIBIT 3, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

August 6, 1968

Mr. H. W. Martin,
Industrial Property
& Contracts Manager
Glaxo Group Limited
Clarges House
6-12 Clarges Street
London, W. 1, England

Dear Mr. Martin:

Thank you kindly for your reply to our request for licensing Griseofulvin.

We are aware that there is some type of litigation going on between your firm and the United States Justice Dept.; therefore, we do understand your request to delay such a decision. We only ask and appreciate any encouraging information that you may be able to send us in the affirmative for such a license.

I can assure you that our firm will withstand rigid examination and that we can expand the Griseofulvin market.

Thank you for your kind attention to this matter.

Sincerely yours,

DOONER LABORATORIES, INC.
EUGENE C. DOONER, JR.
President

EXHIBIT 4, ANNEXED TO DOONER, AFFIDAVIT OF JUNE 5, 1970

September 6, 1968

Mr. H. W. Martin,
Industrial Property & Contracts Manager
Glaxo Group Limited
Clarges House
6-12 Clarges Street
London, W. 1, England

Dear Mr. Martin:

As further evidence of our decision to obtain a license for Griseofulvin in the United States I think that your serious consideration of my proposal at this time would be mutually beneficial.

Obviously we would expand the market but, most of all your willingness to grant a license to Dooner Laboratories, Inc. would be looked upon quite favorably by the United States Justice Dept. and other prominent government agencies who would have an interest in the future of small businesses.

We thank you in advance for your consideration.

Sincerely yours,

DOONER LABORATORIES, INC.
EUGENE C. DOONER, JR.
President

EXHIBIT 5, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

September 16, 1968

Mr. H. W. Martin,
Industrial Property & Contracts Manager
Glaxo Group Limited
6-12 Clarges Street
London, W. 1, England

Dear Mr. Martin:

One of the three United States licensees marketing Griseofulvin has agreed to sell Dooner Laboratories the bulk chemical. A copy of the agreement will be sent to you on request. However, the price quoted is a bit higher than the price on a direct basis from Glaxo or ICI. In view of this price I am investigating optional sources at more reasonable prices.

Prior to going to Italy, Japan and possibly Russia for this chemical would you be kind enough to review my earlier requests to purchase this chemical from Glaxo.

Your consideration is appreciated.

Sincerely yours,

DOONER LABORATORIES, INC.
EUGENE C. DOONER, JR.
President

EXHIBIT 6, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

October 2, 1968

Mr. H. W. Martin
Industrial Property &
Contracts Manager
Glaxo Group Limited
6-12 Clarges Street
London, W. 1, England

Dear Mr. Martin:

I have attempted to purchase bulk griseofulvin from both McNeil Laboratories and Schering. Both companies replied in the negative stating that their business is primarily selling fabricated products.

This firm still has an interest in obtaining marketing rights direct from Glaxo and at the present time without making any commitments would you consider selling us five kilos of micro crystalline griseofulvin, so that we can institute appropriate Food and Drug Administration studies.

Your consideration of this request is appreciated.

Sincerely yours,

DOONER LABORATORIES, INC.
EUGENE C. DOONER, JR.
President

EXHIBIT 7, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

GLAXO GROUP LIMITED
CLARGES HOUSE, 6-12 CLARGES STREET, LONDON, W. 1

Eugene C. Dooner, Esq.,
Dooner Laboratories Inc.
P.O. Box 909,
Haverhill,
Massachusetts 01830,
U.S.A.

19th December, 1968.

Dear Mr. Dooner,

First may I apologise for not replying to your last letter concerning your interest to purchase bulk supplies of Griseofulvin.

After careful consideration of the commercial aspects of our supplies of Griseofulvin, we are quite convinced that our existing distribution arrangements in the U.S.A. are entirely satisfactory. Therefore, with regret, I have to inform you that we would not wish to enter into supply transactions of bulk Griseofulvin at the present time.

Although your previous correspondence makes reference to the fact that we are involved in litigation in the U.S.A. concerning Griseofulvin, I can assure you that we have not been influenced in any way by this in coming to a decision which is based solely on commercial considerations.

Yours sincerely,

H. W. MARTIN,
Industrial Property & Contracts Manager.

EXHIBIT 8, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

December 31, 1968

Mr. H. W. Martin,
Industrial Property & Contracts Manager,
Glaxo Group Limited,
Clarges House,
6-12 Clarges Street,
London, W. 1, England

Dear Mr. Martin:

Thank you for your reply concerning the request for Dooner Laboratories, Inc. to acquire a license from your firm to market Griseofulvin.

Dooner Laboratories, Inc. is a new, aggressive pharmaceutical firm with modern manufacturing and production facilities. Our new premises were occupied on September 5, 1968.

I know the Griseofulvin market well and can assure you that this firm (if given such a license) will expand the U. S. market.

Mr. Behrakis, a Vice President of Dooner Laboratories will be in Europe sometime in the near future and I was wondering if he might request a personal interview with you to discuss the matter further.

Please advise.

Sincerely yours,

DOONER LABORATORIES, INC.
EUGENE C. DOONER, JR.
President

EXHIBIT 9, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

GLAXO GROUP LIMITED
CLARGES HOUSE, 6-12 CLARGES STREET, LONDON, W. 1

Mr. E. C. Dooner, Jr.
Dooner Laboratories Inc.
P.O. Box 909,
Haverhill,
Massachusetts 01830,
U.S.A.

13th February, 1969.

Dear Mr. Dooner,

I have to acknowledge your letter of 31st December 1968, and apologise for the delay in replying which has been occasioned by a somewhat protracted overseas visit.

With regard to your request that we should meet your Mr. Behrakis during his forthcoming visit to Europe, I would say that in earlier correspondence I have indicated the outcome of our consideration of your request for a license under our griseofulvin patents. However, if you feel that any useful purpose would be served, we should be quite willing to see Mr. Behrakis here in London.

Yours sincerely,

H. W. MARTIN,
Industrial Property & Contracts Manager.

EXHIBIT 10, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

May 4, 1970

Glaxo Group Limited
Clarges House
6-12 Clarges Street
London, W. 1, England

Gentlemen:

On several occasions this firm has made attempts to obtain Griseofulvin.

The only positive reply was from Ayerst Laboratories and the price quoted was considered too high.

This letter is written to you once again as a request to purchase the chemical at the same price as you sell to other accounts in the United States.

Your kind consideration of the request is deeply appreciated.

Your very truly,

DOONER LABORATORIES, INC.
EUGENE C. DOONER, JR.
President

EXHIBIT 11, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

June 27, 1968

Mr. Harry McNey, President
McNeil Laboratories, Inc.
Port Washington, Pa. 19304

Dear Harry:

Since Glaxo Laboratories no longer restricts their licensees from reselling bulk griseofulvin our firm would like to purchase this item from McNeil Laboratories, Inc.

We are interested in the micro crystalline and regular particle size.

Would you kindly quote prices and terms.

Your very truly,

DOONER LABORATORIES, INC.
EUGENE C. DOONER, JR.
President

EXHIBIT 12, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

McNeil Laboratories, Inc.
CAMP HILL ROAD, FORT WASHINGTON, PA. 19034

July 10, 1968

Mr. Eugene C. Dooner, Jr.
President, Dooner Laboratories, Inc.
P. O. Box 909
Haverhill, Massachusetts 01830

Dear Gene:

In reply to your letter of June 27, 1968, requesting prices for bulk griseofulvin, we wish to state that we are a manufacturer and seller of pharmaceutical preparations in finished dosage forms and are not engaged in the business of selling chemicals in bulk.

Very truly yours,

McNEIL LABORATORIES, INC.
Harry W. McNey
President

EXHIBIT 13, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

June 27, 1968

Dr. D. R. Longman,
V. P. and General Mgr.
Schering Corp.
60 Orange Street
Bloomfield, N. J. 07003

Dear Doctor Longman:

Since Glaxo Laboratories no longer restricts their licensees from reselling bulk griseofulvin our firm would like to purchase this item from Schering Corp.

We are interested in the micro crystalline and regular particle size.

Would you kindly quote prices and terms.

Yours very truly,

DOONER LABORATORIES, INC.
EUGENE C. DOONER, JR.
President

EXHIBIT 14, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

SCHERING

SCHERING CORPORATION, BLOOMFIELD, N.J. 07003

July 3, 1968

Mr. Eugene C. Dooner, Jr.
President
Dooner Laboratories Inc.
P. O. Box 909
Haverhill, Massachusetts 01830

Dear Mr. Dooner:

This is in response to your letter of June 27 concerning bulk griseofulvin.

Since our purchases of griseofulvin substance are solely for the production of our own line of pharmaceutical products, we are not in a position to quote prices to you on this item.

Sincerely yours,

DONALD R. LONGMAN
Vice President
Domestic Operations

EXHIBIT 15, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

June 28, 1968

Mr. Charles Johnson, President
Ayerst Laboratories
685 Third Avenue
New York, New York 10017

Dear Mr. Johnson:

Since Imperial Chemical Industries no longer restricts their licensees from reselling bulk griseofulvin our firm would like to purchase this item from Ayerst Laboratories.

We are interested in the micro sized and regular particle size.

Would you kindly quote prices and terms.

Yours very truly,

DOONER LABORATORIES, INC.
EUGENE C. DOONER, JR.
President

EXHIBIT 16, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

AYERST LABORATORIES
DIVISION OF AMERICAN HOME PRODUCTS CORPORATION
685 Third Avenue, New York, N.Y. 10017

July 19, 1968

Mr. Eugene C. Dooner, Jr.
President
Dooner Laboratories Inc.
P. O. Box 909
Haverhill, Massachusetts 01830

Dear Mr. Dooner:

Thank you for your letter of June 28th, inquiring as to the prices and terms we would quote for bulk griseofulvin. We would be interested in selling griseofulvin in bulk, and we would ask that you supply us with the following information:

1. Has your facility been registered with the Food and Drug Administration, and, if so, please supply the registration number;
2. Have you a New Drug Application approved by the Food and Drug Administration covering the sale by you of griseofulvin; and
3. Would you supply us with some idea of the amount of bulk griseofulvin you will require.

Since your firm is not known to me, may I request that you supply appropriate trade references.

Very truly yours,
C. M. JOHNSON

EXHIBIT 17, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

August 8, 1968

Mr. C. M. Johnson, President
Ayerst Laboratories
685 Third Avenue
New York, New York 10017

Dear Mr. Johnson:

I appreciate your willingness to sell Griseofulvin to Dooner Laboratories, Inc. and in answer to your questions:

1. Our FDA Registration No. is 12-16241.
2. We are applying for a Form 6 application which will allow us to market the finish product provided we supply the Food & Drug Administration with appropriate blood studies.
3. Quantities desired would be 250 kilos per order.

Our firm is new and has been in existence one year. We have new and modern facilities in Haverhill, Massachusetts. The plant has complete facilities for manufacturing and quality control. The chemistry labs contain the very latest in laboratory equipment and our research facilities will be limited only by our imagination and budgets.

I believe any drug wholesaler in Massachusetts will identify us or you may try the National Pharmaceutical Council in Washington, D. C.

Your price quotation for the raw material in this quantity would be appreciated.

Thank you for your courtesies and consideration of our request.

Yours very truly,

DOONER LABORATORIES, INC.
EUGENE C. DOONER, JR.
President

EXHIBIT 18, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

AYERST LABORATORIES
DIVISION OF AMERICAN HOME PRODUCTS CORPORATION
685 Third Avenue, New York, N.Y. 10017

September 4, 1968

Mr. Eugene C. Dooner, Jr., President
Dooner Laboratories Inc.
P.O. Box 909
Haverhill, Massachusetts 01830

Dear Mr. Dooner:

Your letter of August 8 has been referred to me for reply and in response thereto I am pleased to quote you a price of $117.70 per kilogram of Griseofulvin (regular size), f.o.b. Rouses Point, New York, net 30 days. We are prepared to ship the 250 kilograms specified in your letter within sixty days following acceptance of this order.

Should you decide to place further orders with us, we would require at least 90 days for shipment.

We look forward to hearing from you.

Very truly yours,

WILLIAM L. DAVIS

EXHIBIT 19, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

IMPERIAL CHEMICAL INDUSTRIES LIMITED
PHARMACEUTICALS DIVISION
ALDERLEY HOUSE, ALDERLEY PARK, MACCLESFIELD, CHESHIRE

Dooner Laboratory Inc.,
Box No. 909,
Haverhill,
Massachusetts,
U S. A.

25th September 1968

Dear Sirs,

GRISEOFULVIN

Our colleagues in ICI America Inc. have told us of your approach to them with regard to supplies of griseofulvin in bulk.

May we please take this opportunity of advising you that the distribution of this product in the U.S.A. is undertaken on our behalf by Ayerst Laboratories Inc. in whom are vested sole distributor rights.

You will understand, therefore, that we should be grateful if you would kindly address to them any enquiry you may have.

Yours faithfully,

G. H. HOCKNEY
American Manager

EXHIBIT 20, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

November 25, 1968

The Patent Agent
Imperial Chemical Industries Limited
Thames House North
Millbank
London S. W. 1, England

Gentlemen:

Dooner Laboratories, Inc. has recently learned of your desire to license additional companies to sell Griseofulvin in the United States and its possessions.

We are interested in obtaining such a license and would appreciate hearing from you in this regard.

Yours very truly,

DOONER LABORATORIES, INC.
EUGENE C. DOONER, JR.
President

EXHIBIT 21, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

IMPERIAL CHEMICAL INDUSTRIES LIMITED
PHARMACEUTICALS DIVISION
ALDERLEY HOUSE, ALDERLEY PARK, MACCLESFIELD, CHESHIRE

Dooner Laboratories Inc.,
P.O. Box 909,
Haverhill,
Massachusetts 01830,
U.S.A.

10th December 1968

Dear Sirs,

Griseofulvin: U.S. Patent 2,900,304

Your letter of 25th November 1968 has been passed to us by our Patent Agent in London.

We are prepared to grant non-exclusively a full and unrestricted licence under the above numbered U.S. Patent to all suitable applicants. The royalty will be 5% of the aggregate net invoiced sales value of griseofulvin sold by the licensee under the licence during the life of the patent.

Will you please let us know if you wish to obtain a licence on these terms and confirm that your firm and premises are approved under Federal Food and Drug Regulations. We will thereupon send you a form of license.

Yours faithfully,

Imperial Chemical Industries Limited,
T.W.M. BLAND,
Pharmaceuticals Division Secretary.

EXHIBIT 22, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

December 20, 1968

Imperial Chemical Industries Limited
Pharmaceuticals Division
Alderley House, Alderley Park
Macclesfield, Cheshire
England

Gentlemen:

Thanks for your reply regarding a U.S. licensing arrangement for griseofulvin.

Our firm is very much interested but would like a few more particulars regarding price and delivery time. We would also like to know if you plan to extend additional discounts for material that is used to fill government contracts?

Our firm and premises are approved by the Food and Drug Administration. Our registration number is 12-16241.

Thanks again for your assistance and we shall anxiously await your reply.

Very truly yours,

DOONER LABORATORIES, INC.
EUGENE C. DOONER, JR.
President

EXHIBIT 23, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

IMPERIAL CHEMICAL INDUSTRIES LIMITED
PHARMACEUTICALS DIVISION
ALDERLEY HOUSE, ALDERLEY PARK, MACCLESFIELD, CHESHIRE

Eugene C. Dooner Jr. Esq.,
President,
Dooner Laboratories Inc.,
P.O. Box 909,
Haverhill,
Massachusetts 01830,
U.S.A.

15th January, 1969.

Dear Mr. Dooner,

Griseofulvin—U.S. Patent 2,900,304

Thank you for your letter of 20th December 1968. I enclose two copies of a draft licence agreement. If you have any comments on this you will no doubt let me know. On the other hand, if the form is acceptable to you, you could execute the two copies and return them to me and I would let you have back one copy executed by ICI.

I should perhaps add that as we have appointed the Ayerst Laboratories Division of American Home Products Corporation sole importers and distributors of our griseofulvin in the U.S.A. we should not be in a position to supply you direct. If, therefore, you do not propose yourselves to undertake manufacture, you will have to obtain your supplies either from Ayerst or some other supplier.

Yours truly,

T.W.M. BLAND,
Division Secretary.

EXHIBIT 24, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

THIS LICENCE AGREEMENT is made the day of 1969 *BETWEEN* IMPERIAL CHEMICAL INDUSTRIES LIMITED (hereinafter called "ICI") of Imperial Chemical House Millbank London S.W.1. England, a corporation registered in England and DOONER LABORATORIES INC. (hereinafter called "the Licensee") of P.O. Box 909 Haverhill Massachusetts U.S.A., a corporation registered in Massachusetts and *WITNESSETH* that

1. ICI hereby grants the Licensee a non-exclusive licence under United States Patent No. 2,900,304 to manufacture process repack and sell dosage forms of griseofulvin. The licence shall continue during the life of the said patent.

2. In consideration of the grant of this licence Licensee shall pay to ICI a royalty of five per cent of the aggregate net invoiced sales value of griseofulvin manufactured processed or repacked and sold by Licensee under and during the currency of this licence.

3. The term "aggregate net invoiced sales value" shall mean the sum of the sales prices invoiced in the period less

(a) returns and allowances;
(b) cash and trade discounts;
(c) delivery charges prepaid or allowed to customers;
(d) excise or other taxes assessed against the manufacture use or sale of the product.

4. Payment of royalty shall be made in United States Dollars to ICI at Alderley House Alderley Park Macclesfield Cheshire England. Payment shall be made quarterly within ninety days of the end of each calendar quarter and shall be in respect of all sales of griseofulvin made by Licensee during the previous calendar quarter.

5. Licensee shall keep adequate records of all griseofulvin sold by Licensee and will when remitting royalties submit a statement showing all such sales during the period to which the royalties relate the aggregate net invoiced sales value thereof and the amount of royalties payable thereon. If no royalties are payable in respect of any particular quarter a statement to that effect shall be submitted in lieu of the foregoing statement.

6. Licensee will as and when requested by ICI make available its records for inspection at any time within

normal business hours by an independent auditor for the purpose of verifying the statements to be provided by the Licensee hereunder. Such auditor shall be appointed by ICI but shall be one to whom the Licensee shall have no reasonable objection and he shall report to ICI only on the amount of royalties due.

EXECUTED by IMPERIAL CHEMICAL INDUSTRIES LIMITED

EXECUTED by DOONER LABORATORIES INC.

7. I.C.I. will hold Dooner harmless and defend Dooner if Dooner, acting under I.C.I. patent (U.S. patent 2,900,304) infringes any patent or process rights of another. I.C.I. to warrant patent is valid and in force.

8. A price schedule is to be defined which can be relied upon whether raw material is purchased direct from I.C.I. or American Home Products (Ayerst Laboratories Division).

9. The "Favored Nation Clause" is to apply whereby I.C.I. at no time will sell to competitors, including Ayerst Laboratories Division of American Home Products at a better price than that offered to Dooner Laboratories, Incorporated.

EXHIBIT 25, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

January 23, 1969

Mr. T.W.M. Bland
Imperial Chemical Industries, Ltd.
Alderley House
Alderley Park, Macclesfield, Cheshire
England

Dear Mr. Bland:

I appreciate the license agreement for United States distribution rights to griseofulvin.

Since Ayerst Laboratories is a competitor and has quoted me an unfavorable price for the raw material I have taken the liberty of adding several protective clauses to the agreement.

I'm sure you will agree that these requests are quite normal and if you approve of the changes we would like to execute a favorable license at the earliest opportunity.

Please advise.

Sincerely yours,

EUGENE C. DOONER, JR.

EXHIBIT 26, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

IMPERIAL CHEMICAL INDUSTRIES LIMITED
PHARMACEUTICALS DIVISION
ALDERLEY HOUSE, ALDERLEY PARK, MACCLESFIELD, CHESHIRE

Eugene C. Dooner, Jr., Esq.,
President,
Dooner Laboratories Inc.,
P.O. Box No. 909,
Haverhill,
Massachusetts 01830,
U.S.A.

13th February, 1969.

Dear Mr. Dooner,

GRISEOFULVIN—U.S. PATENT 2,900,304

Thank you for your letter of 23rd January. I am afraid that we are unable to agree to the three additional clauses that you propose. In place of your proposed Clause 7 we should, however, be willing to insert the following clause:

> "If any claim of U.S. Patent 2,900,304 shall be held invalid the Licensee shall no longer be obligated to pay royalties on account of such a claim."

Because, as I informed you in my letter of 15th January, we are unable to supply you direct, your proposed Clauses 8 and 9 are inapplicable. In any case, we could not accept Clause 8 in that we have no control or knowledge of the price which may be quoted by American Home Products for any sales in bulk of griseofulvin.

Yours truly,

T.W.M. BLAND,
Division Secretary.

EXHIBIT 27, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

May 4, 1970

Imperial Chemical Industries Limited
Pharmaceuticals Division
Alderley Park
Macclesfield, Cheshire
England

Gentlemen:

On several occasions this firm has made attempts to obtain Griseofulvin.

The only positive reply was from Ayerst Laboratries and the price quoted was considered too high.

This letter is written to you once again as a request to purchase the chemical at the same price as you sell to other accounts in the United States.

Your kind consideration of this request is deeply appreciated.

Yours very truly,

DOONER LABORATORIES INC.
EUGENE C. DOONER, JR.
President

EXHIBIT 28, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970

ANKERFARM S.p.A.
VIALE LOMBARDIA, 5-20092 CINISELLO B. (MILANO)

Messrs.
DOONER LABS. Inc.
P. O. Box 909
Haverhill (Mass. 01830)
U.S.A.

14th March, 1969.

Gentlemen:

We acknowledge receipt of your letter dated 14 February, from which we noted with regret that the sample of Griseofulvin micro-crystalline particle quality, previously sent to you has gone astray in the mail.

We have pleasure in enclosing herewith another sample of Griseofulvin micro-crystalline for your evaluation, together with the relative certificate of analysis.

We did not understand whether the material is destined for the U.S. home market or for re-exportation.

In this respect please note that for this product we are not in the position to give F.D.A. certification.

Looking forward to reading you, we remain,

very truly yours,

ANKERFARM
Sales Department

EXHIBIT 29, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

March 25, 1969

Ankerfarm S.P.A.
Viale Lombardia, 5
20092 Cinisello B. (Milano)

Attention Sales Department:

Gentlemen:

Thank you kindly for your sample of micronized griseofulvin and your letter of March 14, 1969.

Our interest in this product is for the United States home market and we are disappointed to learn that the product cannot be certified by F.D.A.

Is there a possibility that this descision can be reversed and that you can apply for F.D.A. certification?

Please advise.

Yours very truly,

EUGENE C. DOONER, JR.
President

EXHIBIT 30, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

ANKERFARM S.p.A.
VIALE LOMBARDIA, 5-20092 CINISELLO B. (MILANO)

April 2, 1969.
AB:ac

Messrs.
DOONER Laboratories
Ward Hill
Haverhill, Mass.
U.S.A.

Dear Sirs,

We regret to inform you that the Griseofulvin we can supply is not under F.D.A. approval and we do not plan, for the moment, to apply for such certification.

We shall remain at your disposal in case you will market the product outside the U.S.A.

With kindest regards,

Yours faithfully

ANKERFARM
Sales Department

EXHIBIT 31, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

NIPPON KAYAKU CO., LTD.
NEW KAIJYO BLDG. 6, 1-CHOME, MARUNOUCHI,
CHIYODA-KU, TOKYO, JAPAN
P.O. Box 262 Tokyo Central
Manufacturers-Exporters

Tokyo, Nov. 5, 1968

Messrs.
Dooner Laboratories Inc.
P.O. Box 909
Haverhill, Massachusetts 01830
U.S.A.

Gentlemen:

We have received your letter of October 18 inquiring for our griseofulvin.

We are sorry to say that Glaxo Laboratories of England has already taken its Patent all over the world. So we refrain from quoting you this product.

Regretting our negative answer in this matter.

Yours truly,

NIPPON KAYAKU CO., LTD.
M. SHIBATA
Chief, Export Section
Pharmaceuticals Division

EXHIBIT 32, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

November 26, 1968

Mr. M. Shibata, Chief
Export Section, Pharmaceuticals Division
Nippon Kayaku Co., Ltd.
New Kaijyo Bldg. 6, 1-Chome, Marunouchi
Chiyoda-Ku, Tokyo, Japan

Dear Mr. Shibata:

Thank you kindly for your reply to our letter requesting the purchase of griseofulvin.

If Dooner Laboratories is willing to offer protection from patent indemnity would you be agreeable to selling us this product?

Sincerely Yours,

DOONER LABORATORIES, INC.
EUGENE C. DOONER, JR.
President

EXHIBIT 33, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

NIPPON KAYAKU CO., LTD.
NEW KAIJYO BLDG. 6, 1-CHOME, MARUNOUCHI,
CHIYODA-KU, TOKYO, JAPAN
P.O. Box 262 Tokyo Central
Manufacturers-Exporters

Tokyo, December 12, 1968

Messrs.
Dooner Laboratories Inc.
P.O. Box 909
Haverhill, Massachusetts 01830
U.S.A.

Dears Sirs,

Your letter of November 26 has been received by us.

We shall quote you griseofulvin only under the condition that you take and manage the risk of possible patent troubles by yourselves.

Hoping to hear from you further, we remain

Yours truly,

NIPPON KAYAKU CO., LTD.
[illegible]
Chief, Export Section
Pharmaceuticals Division

EXHIBIT 34, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

December 20, 1968

Nippon Kayaku Co., Ltd.
New Kaijyo Bldg. 6, 1-Chome, Marunouchi,
P. O. Box 262 Tokyo Central,
Chiyoda-Ku, Tokyo,
Japan

Attention: Chief, Export Section, Pharmaceuticals

Gentlemen:

Dooner Laboratories, Inc. is prepared to accept the liabilities in any patent infringement regarding the purchase of griseofulvin from your firm.

We are primarily interested in the micro sized particle.

In any event, we will be interested in quotes on the regular size particle and/or the micro sized particle.

Yours very truly,

DOONER LABORATORIES, INC.
EUGENE C. DOONER, JR.
President

EXHIBIT 35, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

NIPPON KAYAKU CO., LTD.
NEW KAIJYO BLDG. 6, 1-CHOME, MARUNOUCHI,
CHIYODA-KU, TOKYO, JAPAN
P.O. Box 262 Tokyo Central
Manufacturers-Exporters

Tokyo, January 7, 1969

Messrs. Dooner Laboratories Inc.
P.O. Box 909
Haverhill, Massachusetts 01830
U.S.A.

Dear Sirs,

Thank you for your letter of December 2.

We should like to quote you Griseofulvin through our agent, Koyo Mercantile Company, Ltd. of Tokyo. As to particle, we wish to supply only microsized one. You will soon receive some information from the said firm.

Hoping to hear from you further, we remain,

Yours truly,

NIPPON KAYAKU CO., LTD.
M. SHIBATA
Chief, Export Section
Pharmaceuticals Division

EXHIBIT 36, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

KOYO MERCANTILE COMPANY, LTD.
IMPORTERS, EXPORTERS AND
MANUFACTURER'S REPRESENTATIVE
Sanshin Bldg.
No. 3-1, 2-Chome, Iwamoto-Cho,
Chiyoda-Ku, Tokyo, (Japan)

January 13, 1969

Dooner Laboratories, Inc.
P.O. Box 909
Haverhill, Massachusetts 01830
U.S.A.

Attn: Mr. Eugene C. Dooner, Jr.
President

Gentlemen:

Re: *GRISEOFULVIN*

The letters exchanged between you and Nippon Kayaku Co. on the captioned item have been referred to us for reply, since we are representing Nippon Kayaku for the sale of pharmaceutical products to America.

We are very pleased to note that you are prepared to accept the liabilities in any patent infringement regarding your purchase of the material from us. Under such a condition, and also under the condition that we sell the product without Nippon Kayaku's label and without indicating the manufacturer's name, we are pleased to offer the product as under:

Price: US$85.00/kg CIF by air freight
Packing: 10 kilos per tin
Terms: Letter of Credit to be opened in our favor.

The specification will meet the B.P. specification and the particle size is the micro sized one.

We are interested in knowing what a quantity you have in mind to purchase.

Thanking you and looking forward to the pleasure of hearing from you soon again, we are

Sincerely,

KOYO MERCANTILE CO., LTD.
O. KAEDE
Managing Director

EXHIBIT 37, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

DOONER LABORATORIES INC.

P.O. BOX 909 HAVERHILL, MASSACHUSETTS 01830

January 16, 1969

Mr. M. Shibata
New Kaijyo Bldg. 6, 1-Chome, Marunouchi,
Chiyoda-Ku, Tokyo, Japan
P.O. Box 262 Tokyo Central

Gentlemen:

To assist our company in accelerating the marketing of griseofulvin it would be helpful to us to receive the following information.

Have the facilities where this antibiotic is manufactured been approved by the United States Food and Drug Administration?

Please advise.

Yours very truly,

EUGENE C. DOONER, JR.

EXHIBIT 38, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

NIPPON KAYAKU CO., LTD.
NEW KAIJYO BLDG. 6, 1-CHOME, MARUNOUCHI,
CHIYODA-KU, TOKYO, JAPAN
P.O. Box 262 Tokyo Central
Manufacturers-Exporters

Tokyo, Jan. 30, 1969

Messrs. Dooner Laboratories Inc.
Haverhill, Massachusetts 01830
P.O. Box 909
U.S.A.

Gentlemen:

Re: Griseofulvin

Your letter of January 16 has been received by us.

We are pleased to advise you that our facilities where the above antibiotic is manufactured have not been approved by the United States Food and Drug Administration.

We remain

Yours truly,

NIPPON KAYAKU CO., LTD.
[illegible]
Chief, Export Section
Pharmaceuticals Division

EXHIBIT 39, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

February 5, 1969

Nippon Kayaku Co., Ltd.
New Kaijyo Bldg. 6, 1-Chome, Marunouchi,
P.O. Box 262 Tokyo Central
Chiyoda-Ku, Tokyo, Japan

Gentlemen:

In regards to your letter of January 30, 1969. Would the plant where this material is manufactured agree to an inspection by the U.S. Food and Drug Administration? Please advise.

Yours very truly,

EUGENE C. DOONER, JR.
President

EXHIBIT 40, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

NIPPON KAYAKU CO., LTD.
NEW KAIJYO BLDG. 6, 1-CHOME, MARUNOUCHI,
CHIYODA-KU, TOKYO, JAPAN
P.O. Box 262 Tokyo Central
Manufacturers-Exporters

Tokyo, February 21, 1969

Messrs.
Dooner Laboratories, Inc.
Ward Hill, Haverhill,
Massachusetts 01830
U.S.A.

Gentlemen:

Re: Griseofulvin

We have received your letter of February 5.

Generally speaking, it seems to be very expensive to have an inspection by F.D.A. It is said that the company to undergo an inspection must pay traveling expenses or hotel charge of inspectors. So we wish to study this problem only on condition that we are not charge any such cost.

We remain

Yours truly,

NIPPON KAYAKU CO., LTD.
[illegible]
Chief, Export Section
Pharmaceuticals Division

EXHIBIT 41, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

February 28, 1969

Nippon Kayaku Co., Ltd.
New Kaijyo Bldg. 6, 1-Chome,
Marunouchi, Chiyoda-Ku
Tokyo, Japan
P.O. Box 262 Tokyo Central

Gentlemen:

We realize that the cost of a plant inspection on foreign soil by the United States Food & Drug Administration must be borne by the person or persons requesting such an inspection.

Dooner Laboratories would be willing to absorb these costs providing Nippon Kayaku Co., Ltd. will reimburse these costs over a reasonable period of time. The rebate can be deducted from the price of the raw material. Such rebates to amount to no more than 15% of the cost of the FDA inspection per shipment of griseofulvin.

Should you agree to the above conditions and the findings of the FDA inspection are negative or for other reasons Dooner Laboratories elects not to purchase said chemical (griseofulvin) from Nippon Kayaku Co., Ltd. then all such obligations shall cease.

Dooner Laboratories will have absorbed the entire cost and we will not request any payments from Nippon Kayaku Co., Ltd.

Yours very truly,

EUGENE C. DOONER, JR.
President

EXHIBIT 42, ANNEXED TO DOONER AFFIDAVIT OF JUNE 5, 1970.

NIPPON KAYAKU CO., LTD.
NEW KAIJYO BLDG. 6, 1-CHOME, MARUNOUCHI,
CHIYODA-KU, TOKYO, JAPAN
P.O. Box 262 Tokyo Central
Manufacturers-Exporters

Tokyo, March 12, 1969

Messrs.
Dooner Laboratories, Inc.
Ward Hill, Haverhill
Massachusetts 01830
U.S.A.

Gentlemen:

With thanks, we have received your letter of February 28, and noted the contents.

In conclusion, we are sorry to say that we can not accept your proposal. It is sure the problem of the F.D.A. inspection is big abstraction.

Regretting our negative answer, we remain

Yours truly,

NIPPON KAYAKU CO., LTD.
[illegible]
Chief, Export Section
Pharmaceuticals Division

AFFIDAVIT OF HAROLD SNYDER,
DATED JUNE 17, 1970.

[CAPTION OMITTED]

1. I am the President of Biocraft Laboratories, Inc., 92 Route 46, East Paterson, New Jersey 07407. I have been in the pharmaceutical business for about sixteen years. In about 1950 I began working for United States Testing Company, Hoboken, New Jersey, as a chemist and bacteriologist. In 1954 I left United States Testing Company to take a job as a chemist and bacteriologist for a small pharmaceutical manufacturing company. Within about five years I progressed to a management position with the company, and since that time I have been employed or self-employed in a management capacity with various pharmaceutical companies. In 1964 I started my own manufacturing company, Biocraft, which my wife and I wholly own.

2. Biocraft is engaged primarily in the business of buying antibiotics in bulk, converting them into dosage form, and selling the packaged product to other pharmaceutical companies which distribute the finished packaged product. Biocraft presently has approximately 26 employees. Its total sales in 1969 were approximately $2.6 million. Its total assets are approximately $1.1 million. Biocraft is fully certified by the Food and Drug Administration and is regularly inspected by it. Biocraft fully meets the high standards of the Food and Drug Administration, and it has an excellent record of quality control.

3. Biocraft is listed with the Food and Drug Administration as a manufacturer. Its business consists of converting bulk pharmaceuticals into dosage form, packaging and labeling same, and selling the finished product to others as previously indicated. Biocraft has a number of major national drug firms as customers, for whom it manufacturers antibiotic-containing drugs. ("Manufacture," in this sense and as used in the previous paragraph, does not mean production of the raw material; it means converting the bulk chemical into finished dosage form, labeling, and packaging same.) We advertise regularly in the "Journal of Pediatrics", "Pediatrics", "The Internist", "Drug Topics", "Physicians Book Compendium" and the "New England Journal of Medicine". Attached to this affidavit

as Exhibits A and B are copies of two of our recent advertisements, showing the names of some of the drug companies which purchase generic penicillin V from us and distribute it under their own names.

4. Biocraft is a generic manufacturer. That means that it does not engage in expensive advertising and promotional activities for trademarked or trade name drugs, as do the giants of the industry. For example, our current advertising budget is in the neighborhood of 1% of sales, as contrasted with a percentage of many times that for the major companies in the industry. Some typical figures for advertising expenditures last year, for major brand companies, were 21% of sales for Sterling Drug, 18% for Miles Laboratories, 16% for Bristol, and 12% for Warner-Lambert and American Home Products (Ayerst and Wyeth). A generic drug company sells in competition with brand name companies by offering a substantially lower price. The mechanics of distribution of generic drugs, in my case, works as follows: I make a product, such as penicillin G, where my cost of materials is $.90 per 100, and I sell it to distributors in quantities of 1,000,000 for about $1.24 per 100. This is a mark-up of somewhat below 40%. This figure, of course, does not include overhead, labor, or other plant costs. The distributor to whom I sell the 100 tablets for the $1.24 rate, sells it to a drug store for about $2.00. A "major brand" product would be sold to the druggist at prices ranging from about $2.75 to about $8.00.

5. Another example is penicillin VK, which I sell to distributors in quantities of 100,000 for $3.60 per 100, which, in turn, are sold by the distributors at approximately $5.75 per 100, less 10% when they purchase ten or more bottles. The major brands, by contrast, sell for $8.95 per 100. The reason that I sell at a substantially lower price than do the major brands is that it is necessary for me to do so in order to meet the propaganda of the major drug companies that their product is superior to generics. I sell "Brand X" in competition with a major brand name, where my Brand X is chemically identical, perhaps even superior, to the highly advertised competition, but because I am selling Brand X I have to sell it at a considerably lower price in order to get anywhere in the marketplace.

6. The examples given above apply to penicillin, an antibiotic drug, which in my view, is similar from a marketing

standpoint to griseofulvin. I became interested in the marketing possibilities of griseofulvin in April 1969, after reading in the "Pink Sheet" (a drug industry trade publication) that Imperial Chemical Industries was prepared to grant licenses for griseofulvin as a result of some government litigation involving the patents. Although the $10 million annual market for this product is not a very large one, it seemed to me that my company could capture 10% of that market; and an additional $1 million in sales would not be insignificant to us. Therefore, the product seemed to offer interesting possibilities for a competitively-oriented firm like mine.

7. Consequently, I wrote a letter to Imperial Chemical Industries in England, requesting a license to manufacture griseofulvin in dosage form (attached to this affidavit as Exhibit C). They responded by letter of May 5, 1969, offering me a license at a royalty rate of 5% of net sales (letter attached as Exhibit D).

8. I considered, but rejected, the idea of fermenting griseofulvin and thus manufacturing it from the very beginning. I rejected this approach because the $10 million a year market for the product, considered together with the percentage of it that I could capture and the cost of installing the necessary fermentation facilities, did not justify the necessary investment. I, therefore, decided that the only way I could market the product would be to buy it in bulk form, in the manner I have previously described for penicillin products. I, therefore, telephoned Mr. Maynard, ICI's patent agent in England, in order to buy "griseofulvin". He referred me to Mr. Mollob of Ayerst in Rouse's Point, New York, whom I then telephoned. Mr. Mollob advised me to speak to Mr. Goetchus, Ayerst's Director of Product Coordination, whom I subsequently contacted for a price quotation.

9. In response to my request for a price quotation, Mr. Goetchus advised that Ayerst was prepared to sell to Biocraft the finished capsule form of griseofulvin at a price of, I recall to be, $50 per 1000 in quantities of 500,000. I telephoned Mr. Goetchus and advised that the quotation was out of line with the current drug store selling price of about $28 per bottle of 250. At this time the established sellers of the product, Schering, McNeil and Ayerst, were quoting drug stores a price in the neighborhood of about

$28 per 250 (250mg tablets) or $112 per 1000. Mr. Goetchus responded that that was his company's price, and that he would not quote a lower one.

10. The price quotation given in the previous paragraph, $50 per 1000 of 250mg. capsules, given the pricing and distribution structure I have previously described in this affidavit, requires Biocraft to sell to a distributor at a price of about $80 per 1000. A 5% royalty under the ICI license would have to be added onto this, making the price to the distributor approximately $84 per 1000. The price of Schering and the other established firms is about $112 per 1000. This leaves a $28 spread between the $84 price I could charge to distributors and the $112 price that the brand-name firms charge to drug stores. The $28 spread amounts to a differential of approximately 25% of the brand-name price, which is much too low to induce the distributor to distribute my product. The kind of differential necessary for me to market my product competitively (except for certain antibiotics in great demand, such as ampicillin) is a differential which permits my product to be distributed for two-thirds the price of the brand-name product.

11. I understand that the going market price for bulk form (microsize) griseofulvin is in the neighborhood of $60 per kilogram. The trouble is that the only companies that can buy it at this price are Ayerst, McNeil and Schering —not Biocraft. If I were on the same basis as these companies, I would be able to market microsize griseofulvin at the same price Ayerst is willing to sell it to me—or even less. This would mean that I would have a real chance to sell the product to the distributor because I then could offer the kind of price differential below the brand-name product that is necessary to distribute the generic product. This result would be that consumers in the United States would have the benefit of my generically labeled product, which is every bit as good as the brand-name product—but the price to the consumer would be much lower.

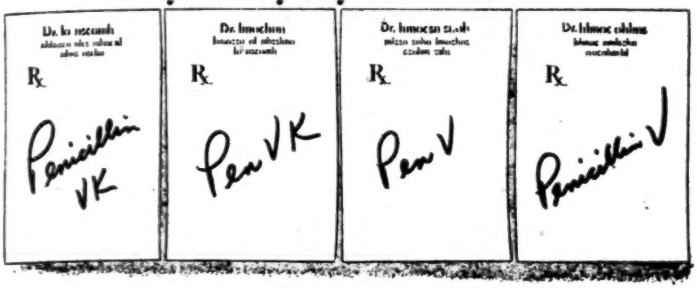
/s/ Harold Snyder

EXHIBIT B, ANNEXED TO SNYDER AFFT. OF JUNE 17, 1970.

EXHIBIT B, ANNEXED TO SNYDER AFFT. OF JUNE 17, 1970

BE READY!

4 Ways a busy Physician Will Write



Generic

Penicillin VK

Potassium Phenoxymethyl Penicillin

Available in convenient, palatable, reconstitutable, 80 cc. and 150 cc. pediatric powders; each 5 cc. dose containing 125 mg. (200,000 units) or 250 mg. (400,000 units) and tablets containing 125 mg. (200,000 units) 250 mg. (400,000) units and 500 mg. (800,000 units).

Manufactured by BIOCRAFT LABORATORIES, INC., East Paterson, N.J. 07407 for:

CALIFORNIA: B & B Laboratories, Beverly Medical, H R. Cenci Laboratories, Inc., Daylin Medical & Surgical Supply Co., General Medical Supply, Hilico Drug Distributors, Fenta Products, Rahn Winters Div., Robinson Laboratory, Inc., United Pharmaceutical. CONNECTICUT: H. L. Moore Drug Exchange. FLORIDA: Barry Martin Company, Generix Drug Sales, Gulf Coast Drug. HAWAII: Arao Laboratories, Inc., Generic Pharmaceutical. RHODE ISLAND: Midway Medical Company. MARYLAND: Barre Drug Company, Carroll Chemical Co., Cumberland Pharmacal, Reyman Drug Co., MASSACHUSETTS: Croydon Browne. MICHIGAN: Cooper Drug Company, Diacin Chemical Co., Wayne Laboratories, NEW JERSEY: Bonders Laboratories, Inc., Supreme Pharmaceutical. NEW YORK: Bioline Laboratories, Inc., Columbia Medical Company, Consolidated Midland Corp., Darby Drug Co., Halsey Drug Company, Interstate Drug Exchange, Jenkins Laboratories, Rawan Pharmacal, Scheinn Surgical, Sherry Pharmaceutical, Spencer Mead, Inc., Vitafort Products, Winsale Drug Company. NORTH CAROLINA: Southern State Pharmaceutical Co. Wayne Medical Company. OHIO: T. J. Brown, Standex Laboratories, Toledo Pharmaceutical. WISCONSIN: Taylor Drug Company, Werner Laboratories, Inc.

as advertised in Drug Topics

AFFIDAVIT OF HAROLD SNYDER, DATED DECEMBER 14, 1970

[Caption Omitted]

1. I am the President of Biocraft Laboratories, Inc., 92 Route 46, East Paterson, New Jersey 07407. I have previously furnished an affidavit (dated June 17, 1970) which was filed in this case. I have examined the prehearing brief of defendant ICI and the attached affidavits recently filed in this case. At pages 21-24 of the brief, counsel for ICI states that the data in my previous affidavit is "inaccurate." It appears to me that ICI has completely misconstrued my statements and has left the Court with a wholly erroneous impression concerning the business involved. My purpose in furnishing this affidavit is to assist the Court, to the extent that I am able to do so, in understanding the facts involved.

2. The figures and computations on pages 22-23 are based on a misconception of Biocraft's business. Biocraft is not a distributor or wholesaler. It is a generic manufacturer. As such, it sells products in finished dosage form to distributors (under the distributor's labels) who, in turn, resell to retail druggists. In its computations, ICI has completely left the distributor step out of its calculations and has operated on the mistaken idea that Biocraft sells directly to the retail druggist. As a result, when ICI says that "supplies of microsized griseofulvin, both bulk and dosage form, are available at commercially viable prices, within the framework of the existing ICI-Ayerst exclusive distributorship relation," they are completely mistaken.

3. ICI bases its statement that microsize griseofulvin is available in bulk form at a "commercially viable price" on the statements in the Ayerst affidavit that Ayerst has quoted the product at $135 per kilogram. If I were to purchase microsize griseofulvin from Ayerst at $135 per kilogram, the price for a bottle of 100 capsules, of 250 mg. each, would work out as follows:

Cost of materials (250 mg., including 3% loss)	$3.48
Cost of capsules	.20

Balance of material (bottles, caps, certifications, cotton, excipients, labels, package insert, etc.)	.15
Total Cost	$3.83 per 100 capsules

Using a 40% gross margin factor (which would include costs of labor, plant overhead, return on investment, financing, etc.), this would result in a price to the distributor of $6.38. The latter is the price the distributor would pay me. He would normally add his own markup onto this, in order to sell to the retail druggist at a profit. At the same time, however, in order to induce the retail druggist to carry a generic product of this type, he would have to quote the druggist a price no more than two-thirds of the price of the equivalent brand-name product. In the case of griseofulvin, the price for a bottle of 100 capsules, 250 mg. each, is about $12.00 (Ayerst price in current *Drug Topics*, $12.14). Thus, the competitive price for generic griseofulvin would have to be $8.00 or less per bottle of 100, while the distributor would be paying me $6.38. The $1.62 spread, which represents a 20% margin for the distributor, is much too low to make it worth the distributor's while to carry my generic product, versus the brand-name product of Ayerst, Schering, or Johnson & Johnson. This $1.62 is hardly sufficient to cover the costs of freight, overhead, etc. On the other hand, if the distributor tried to charge the druggist more than $8.00 in order to increase his margin over $1.62, it would be much more difficult to sell any appreciable amount of the product. This is illustrated by Zenith's sales (as stated by ICI) of less than 500,000 capsules a year. According to the current *Drug Topics*, Zenith's price to the druggist per hundred capsules is $9.85. This represents less than 1% of the griseofulvin market. In short, the iron laws of business make $135 per kilogram much too high a price to be considered "commercially viable," as ICI claims.

4. Similarly, according to ICI's calculations on the basis of the present Ayerst dosage form price, it is stated that "Biocraft is in a position to sell the capsules to a distributor at $76.30 per 1000, which would give the distributor a 32% spread of the retail price—a rather close approxima-

tion to the 33⅓% taken out of the air by Biocraft." Accepting ICI's calculations, once again, ICI is missing the whole point. The $76.30 per thousand price does give a spread of about 32%. This "spread" has to cover both the 33⅓% differential between the prices of the brand-name and generic products and the distributor's own margin. This means that if the distributor sold to the retail druggist at a minus 1⅓% profit, then he could induce the retailer to carry my product. The cold facts of the selling of generic drugs are that the retail druggist must have the 33⅓% for himself, and the distributor must have a margin in addition to this. Even on the basis of ICI's new calculations of the price structure in the market, it is impossible for me to buy griseofulvin in capsule form from ICI's distributor and resell the griseofulvin except at a loss.

5. ICI says that Biocraft makes a "bland assertion that it can obtain 10% of the market" by charging lower prices than the present licensees of the defendants in this case, Ayerst, Schering, and Johnson & Johnson, the brand-name sellers. ICI pooh-poohs this statement and calls it a "rosy prediction." According to the figures in the ICI affidavit, attached to its brief, Glaxo sells bulk griseofulvin (micro-size) at about $60 per kilogram; ICI at $78. At those prices per kilogram, Biocraft would be able to deliver griseofulvin capsules to the distributor at about $3.09 per 100 250 mg. capsules ($60 kilo price for bulk) or $3.85 per 100 250 mg. capsules ($78 kilo price for bulk). At that price level, the distributor could sell to the retail druggist at considerably less than two-thirds of the defendants' licensees' current $12 per 100 capsules of 250 mg. price and still make a handsome profit. Based on my experience with penicillin and other antibiotic drugs, price reductions of this type would enable Biocraft to capture a dramatic share of the market. I would say that my former estimate of capturing a 10% market share was extremely conservative, and I probably could do much better unless the defendants chose to decrease their own profits by deflating their prices and by meeting mine. In either event, the members of the public would be the beneficiaries.

In reading over the papers in this case, it seems to me that the defendants are trying to give the Court the impression that Biocraft or other generic sellers of drugs want the Court to go into the business of fixing prices for the in-

dustry for determining margins of profit as between us and the brand-name sellers. Nothing could be further from the truth. Speaking for Biocraft, at least, I assure the Court that we do not want anything of the kind. All we want is to be treated without discrimination. We don't want the Court to determine what price ICI will charge Ayerst or what Ayerst will charge us or anybody else. What we request is that, as buyers, we be treated on a fair, equal, and non-discriminatory basis—rather than that the defendants follow the principle that big companies deserve a lower price than small ones, such as ourselves.

/s/ HAROLD SNYDER

AFFIDAVIT OF CHARLES W. WHITMORE, DATED DECEMBER 14, 1970

[Caption Omitted]

1. I am associated with and am an employee of Owen Laboratories, Inc. ("Owen"), Belt Line Road at Inwood Road, Dallas, Texas, and am a minority shareholder therein. I began serving as a consultant for Owen on a irregular basis about five years ago and have been employed by Owen since February 1, 1968, as a medical consultant. My principal duties involve consulting for Owen on a broad range of business and professional matters, including Food and Drug Administration and other regulatory matters, marketing, product selection and professional dermatological matters.

2. I received a degree of Doctor of Medicine from the University of Virginia in 1947, and, after serving four years with the Public Health Service, returned there for three years as a resident physician in dermatology. In 1954 I was certified by the American Board of Dermatology and have been a practicing dermatologist since then. In my practice at 2544 Langhorne Road, Lynchburg, Virginia, I have treated more than 30,000 persons.

3. I am also an attorney, having received my law degree from George Washington University in 1951, and am a member of the Virginia Bar.

4. Owen is a small independent dermatological pharmaceutical firm. It was originally incorporated under the laws of Texas in 1946 as Eastern Pharmaceutical Company, and its present name was adopted in January 1963. Owen engages primarily in the business of developing and marketing pharmaceuticals and converting basic bulk chemicals to finished dosage form dermatological pharmaceuticals. Owen presently has between 90 and 100 employees, and occupies modern new facilities of 60,000 square feet. Its sales for the fiscal year ended June 30, 1970, were approximately $3 million. Owen is regularly inspected and fully certified by the Food and Drug Administration and has an excellent record of quality control. It employs one pharmacist, two chemists, and one bacteriologist for this purpose, as well as for research.

5. Owen markets all of its dermatological products under its own tradenames, rather than generically. Owen adver-

tises dermatological pharmaceuticals in "Drug Topics," "Archives of Dermatology," and "Journal of Investigative Dermatology," and displays and promotes at dermatological medical conventions. The company distributes its products primarily through drug wholesalers, who in turn sell the products to retail drugstores.

6. Owen actively and aggressively markets its dermatological pharmaceutical products and our sales are increasing at an annual rate of 25%. Owen's average market share of dermatological products that it markets, where there are competitive products, is 20%. Owen concentrates its dermatological pharmaceutical marketing effort on the some 3,000 practicing dermatologists in the United States. In this connection, Owen employs 15 detail men who each regularly visit approximately 200 dermatologists; Owen does not solicit sales from general practitioners. We feel we have an advantage over both the large pharmaceutical sellers (such as Ayerst, Schering, and McNeil) and the generic houses, because of our close association with and reputation among practicing dermatologists. Approximately 98% of the practice of a dermatologist is out-patient, prescription work. In our opinion, the dermatologist is the key prescriber in this market. The large drug houses, I believe, do not specialize enough to become closely associated with the needs of the dermatologist. The generic houses cannot, I believe, afford such specialiged personnel as Owen's. Owen is, therefore, in a unique position to sell a dermatological product, such as griseofulvin.

7. Owen is continuously looking for prestige prescription dermatological pharmaceuticals to enhance its reputation as a scientifically oriented dermatological house. Griseofulvin is such a product, ideal for this purpose. Griseofulvin is useful primarily in the treatment of dermatological diseases and is the *only* systemic agent available for the treatment of the most common types of skin fungus infections. Since topical preparations, the only other products available for the treatment of such diseases, cannot penetrate the areas of the nails and hair griseofulvin is the *only* agent which can be used successfully for the treatment of the common fungus infections in these areas. Griseofulvin is, therefore, a unique product with a sizeable market which will not, I believe, diminish in the foreseeable future.

8. Therefore, when in 1968 I read in a drug industry pub-

lication about the government's suit against Glaxo and ICI, relating to griseofulvin, I became interested in obtaining griseofulvin for Owen. Owen felt that with its usual aggressive marketing, and unique relationship with dermatologists, it could rapidly achieve a 10 to 20% penetration of the griseofulvin market, as we customarily do on similar products.

9. With these expectations I called Mr. Timberg, counsel for ICI, and asked him about the availability of griseofulvin. He referred me to Thomas Bland, an officer of ICI in England. I telephoned Mr. Bland and expressed Owen's interest in obtaining griseofulvin. As a result, on March 20, 1969, ICI granted Owen a license under ICI's dosage patent at a 5% royalty, but advised Owen that griseofulvin would be available to us only from ICI's American distributor, Ayerst.

10. I then telephoned Maurice Silverstein, who was then in the Legal Department of Ayerst, and subsequently met with him. At that meeting, I asked him to sell griseofulvin to Owen. Owen does not buy any other of its dermatological products in finished dosage form, and was interested in obtaining the bulk powder or finished dosage form depending on cost considerations. In response, Mr. Silverstein told me Ayerst would sell us dosage form griseofulvin only in 250 mg. capsules, at $46.30 per 1000, in minimum orders of 500,000 capsules. We felt that under the conditions of the griseofulvin market this price was extremely high. Therefore, we tried to convince Ayerst that Owen should be given a lower price, on the ground that marketing through Owen could greatly increase Ayerst's market share because of our unique relationship with dermatologists. Nevertheless, Ayerst declined to reduce the price. Since we greatly desired to market griseofulvin, and since Owen could, with certain amendments, come under Ayerst's New Drug Application, thus allowing us to enter the market immediately, Owen nevertheless accepted the offer and ordered a million capsules on March 10, 1969, hoping for quick market penetration and a subsequent reduction in price. As I shall point out, below, neither hope was ever realized.

11. In my New York visit with Mr. Silverstein, he also told me that Ayerst would soon begin marketing a 500 mg. tablet and asked for a six months marketing lead before considering our request. Since the average daily prescribed

dose of griseofulvin is 500 mg., we were greatly interested in obtaining such a tablet. When I contacted Mr. Silverstein sometime later to obtain the 500 mg. tablet, he had transferred to the marketing department of Ayerst. Ayerst then and to date has declined to sell the 500 mg. tablet to us. Owen has been unable to obtain the 500 mg. tablet. I believe that many dermatologists prefer the 500 mg. tablet and that the 500 mg. tablet is now the standard and largest selling size of griseofulvin. Owen is, therefore, at a serious competitive disadvantage in not being able to offer this alternative size to its customers.

12. Owen distributes its brand of griseofulvin ("grisOwen") through wholesalers to druggists, at a price of $9.25 per bottle of 100 250 mg. capsules (microsize). There must be subtracted from the list price, however, a standard 16⅔% wholesaler discount, so Owen actually receives $7.70 from the wholesaler for each bottle sold to the druggist. Owen pays $4.63 to Ayerst for the 100 capsules and then must also pay for bottling and packaging. This brings Owen's cost of materials to approximately $5.00 per bottle, so that we receive about $2.70 per bottle, to cover marketing, development, plant overhead, return on investment, etc. The latter may be specified more precisely as follows.

13. In August 1970, after marketing grisOwen for a year, Owen conducted a cost analysis of all its products. We determined our total overhead costs as follows: marketing, 40% of net sales; research and development, 15% of net sales; and general, 10% of net sales; for a total of 65% of the per unit net return. In the case of griseofulvin, the overhead cost per bottle is 65% of $7.70, or $5.00. Thus, Owen discovered that with total costs (materials, $5.00; overhead, $5.00) of $10.00 it was losing $2.30 on every bottle of griseofulvin capsules it sold; marketing costs *alone* exceed our margin between cost of materials, including packaging, and selling price. GrisOwen is the only unprofitable active product Owen sells.

14. There are two basic means of penetrating a drug market occupied by established firms. One means is price competition and the second is intensive advertising and promotion including physician sampling of the product. Both market strategies decrease the company's revenue per unit sold, since the former decreases margin from above and

the latter increases costs, thereby decreasing margin from below.

15. Owen tried both means to penetrate the griseofulvin market. Because of Ayerst's $46.30 per 1000 price to us, however, the lowest price at which we felt we could offer our product was $9.25 per bottle of 100 250 mg. capsules (microsize). Subsequent events have shown that the price is too high to enable us to displace or even penetrate significantly the established competition.

16. Owen made its first shipment to wholesalers of grisOwen on August 28, 1969, and aggressively attemped to sell its griseofulvin capsules, until August 1970. We sold $69,000 worth of griseofulvin in the fiscal year ended June 30, 1970. This represented about 2% of Owen's total sales. For the four months ended October 31, 1970, Owen's sales of griseofulvin were $27,000, or about 3% of its total sales. According to the affidavit filed in this case by Maurice Silverstein, Ayerst estimates the annual griseofulvin market to be approximately $7 million. On this basis Owen's share of the market is about 1%. Inasmuch as Owen normally achieves a market penetration of 10 to 20% on new dermatological products, Owen's sales of griseofulvin were extremely low. I attribute this primarily, if not exclusively, to our high cost of materials.

17. When the August 1970 cost analysis showed us that, for every $7.70 that we received per bottle of grisOwen, we accrued $10.00 in charges, so that our net return was minus $2.30, it became clear to us that some immediate change was imperative. Therefore, Owen's Administrative Vice President, Carl Gottwald, telephoned Mr. C. M. Johnson, President of Ayerst, on August 28, 1970 to urge a better price. Mr. Johnson replied that Ayerst could give us no price relief because ICI had a limited capacity and Ayerst could get no price relief from ICI.

18. Because of Ayerst's refusal to give Owen a price reduction after our August 28, 1970, request, Owen made a management decision to cease marketing griseofulvin aggressively. Our detail men were told to cease aggressive promotion of griseofulvin. Sampling, which is such an important part of Owen's normal marketing effort, is no longer done for griseofulvin, because its cost is prohibitive. Owen samples every other of its active dermatological pharmaceutical products. Owen has never been able to

consider, because of our price structure, bidding on government contracts for griseofulvin. These contracts constitute an estimated 10 to 15% of the griseofulvin market.

19. In summary, griseofulvin is a product which Owen is uniquely suited to market aggressively and successfully, and one for which we could and did reasonably anticipate commercial success. But because Owen cannot obtain griseofulvin at an economically or commercially viable price, it has been prevented from achieving the market penetration which it reasonably should have realized. In an affidavit of Maurice Silverstein filed in this case, I have seen mention of the price of $135 per kilo, for orders of 250 kilos of microsize griseofulvin in bulk form. It is said by ICI that "supplies of microsize griseofulvin, both bulk and dosage form, are available at commercially viable prices, within the framework of the existing ICI-Ayerst exclusive distributorship relationship." In the first place, the price of $135 per kilo would not allow Owen to make a profit on griseofulvin. In fact, it would still cause Owen to lose money. Second, for whatever difference it would make (because the price is still much too high to be viable or competitively realistic), the fact is that Ayerst by oversight or otherwise never quoted us any such price, or any price at all on bulk microsize griseofulvin, despite our request to buy the product in bulk from them.

20. Owen will probably continue to carry griseofulvin, and buy it in capsules or bulk from Ayerst, because griseofulvin is a prestige product, and to maintain a full line, but Owen cannot afford to take those steps, given the present price structure, which would allow us to become anything but a very minor factor in this market.

21. In the affidavit of Mr. Bland of ICI, filed in this case, I observed that Schering and McNeil buy griseofulvin from Glaxo at about $60.00 a kilo, and Ayerst buys griseofulvin from ICI at $78.00 a kilo. Such a price would be very attractive to Owen. At such a price, I believe that Owen could successfully market griseofulvin in the manner we originally envisioned. Given a fair, nondiscriminatory price, I am confident that Owen could successfully market this product in competition with Ayerst, McNeil, and Schering, in terms of lower prices and better professional service to the dermatologists.

/s/ CHARLES W. WHITMORE

ANSWER OF THE UNITED STATES DATED AUG. 3, 1970, TO GLAXO'S INTERROGATORY ON BULK SALES RESTRICTIONS

[Caption Omitted]

Counsel for the United States hereby answers as follows defendant Glaxo's interrogatory set forth below:

I. Glaxo's Interrogatory

State, separately as to each company, whether plaintiff knows of any facts which it believes indicate that but for the bulk sales provisions adjudged to be unlawful Glaxo, I.C.I., Schering, Johnson & Johnson, and AMHO would have, or would have been likely to have, offered griseofulvin for sale in bulk form to independent United States third parties prior to March 8, 1968, and for each company as to which the answer is in the affirmative state all facts which plaintiff believes indicate that sales offers would have, or would have been likely to have, been made (a) at or about the price Glaxo charged Schering and Johnson & Johnson, or I.C.I. charged AMHO, or (b) at other prices which would have enabled "generic drug houses" and "private label houses" to compete or (c) at any other prices.

II. Answer of the United States

Defendant Glaxo's question is conjectural, hypothetical, and speculative, because it asks counsel for the government to guess what would have happened, if (contrary to the actual fact) the defendants and their licensees at some time prior to March 8, 1968, had entered into agreements with respect to griseofulvin that did not include the illegal provisions to suppress competition in marketing such product, which they did, in fact, include. Before plaintiff can even reach this hypothetical question, defendant asks that plaintiff first assume that the parties would have entered into the remaining provisions of their griseofulvin agreements, absent their unlawful agreement with one another to restrict bulk sales to "independent United States third parties." This assumption is highly questionable.

First, defendant ICI has sworn to the Court, and the Court has found, that "it is ICI's general, routine practice to include bulk sale restrictions in sales agreements for

all its pharmaceutical products" (*United States* v. *Glaxo Group Ltd.*, 302 F. Supp. 1, 6), indicating that ICI made such unlawful terms necessary conditions to its entering into such agreements. Moreover, when ICI submitted a draft of the 1962 license agreement between ICI and AMHO (Ayerst Div.) to Glaxo for its approval, Glaxo rejected the draft agreement as unacceptable, because, among other things, it would "permit Ayerst to sell in bulk" (GX-9, Wallace Afft. annexed to 11/15/68 Govt. Reply Memo; additional copy annexed hereto as Exhibit A and incorporated by reference herein).

Second, the history of the negotiations between Glaxo, on the one hand, and Schering and Johnson & Johnson on the other hand, prior to the execution of the two Glaxo licenses held by the Court to be in unreasonable restraint of trade (*United States* v. *Glaxo Group Ltd.*, 163 U.S.P.Q. 668), further shows the questionable nature of the assumption that the parties would have entered into these licensing agreements without bulk sales restrictions in them to prevent competition. As reported by Mr. Bide of Glaxo, Mr. Brown of Schering "objected strenuously to Merck" being licensed, on the ground that Merck would "press Glaxo continuously to permit general bulk sales"; both Schering and Johnson & Johnson "impressed upon Mr. Bide" the fact that Glaxo could not expect cooperation from them with Merck as a licensee, and he agreed not to license it (App. A of 7/7/70 Govt. Prehearing Br.). Since Schering and Johnson & Johnson so strongly opposed such "general bulk sales," the assumption that they would have entered into a licensing arrangement not providing for such restrictions on competition is ill-founded. It consequently is speculative to proceed on the assumption that the parties would have entered into any agreement at all, if the illegal portion of the licensing arrangement were deleted.

The remainder of this answer, as set forth below, must thus be considered—in order to avoid distortion thereof or its quotation out of context—in the foregoing context of its hypothetical character and its predication upon premises which lack foundation, because they are contrary to the actual facts. The actual facts are, of course, that the parties did enter into the unlawful conspiracy to prevent sale of bulk griseofulvin to independent parties and they

did not, prior to March 8, 1968, enter into any restriction-free license agreement.

The remainder of this answer must also be viewed in the context that defendant Glaxo's question seeks discovery of matters which the government does not believe to be material nor to constitute any part of the government's affirmative case or burden of proof. Accordingly, the government has not undertaken any detailed investigation into the question of what the defendants and those engaged in an unlawful concert of action with them would or might have done, if, contrary to actual fact, they had chosen not to violate the law; and the facts set forth hereinafter cannot be considered to state exhaustively the full state of affairs obtaining with respect to defendant Glaxo's hypotheticals.

Finally, on July 7, 1970, the government filed a pre-hearing brief and four affidavits with exhibits annexed thereto, concerning the final judgment that the government has proposed as necessary to relieve the public from the burdens of defendants' violations of the antitrust laws. This brief and the accompanying documents set forth the contentions and facts upon which the government presently intends to rely, in support of the proposed final judgment. Accordingly, the interrogatory answer herein must be understood as not to detract from or be in derogation of the contentions and facts set forth therein.

To the extent that even a speculative and conjectural response is possible to such a compound and foundationless hypothetical question, and solely in the context of the entire foregoing background, as set forth above, plaintiff further answers as follows:

First, the fact that the parties entered into the agreement to restrain and suppress bulk sale of griseofulvin to "independent United States third parties" (which we understand to mean independent American drug companies) is itself evidence that their agreements had the desired effect of preventing and suppressing such bulk sale competition.

Second, defendants clearly intended it to have such an effect in this case, and deliberately imposed such restriction for such purpose. In this respect, two high officials of ICI, Messrs. Methven and Bland, discussed with one another the propriety of the restriction against bulk sales to independent American drug companies, that ICI was to

impose on AMHO, and they then agreed to adopt it because Glaxo would impose the same type of bulk sales restriction upon its licensees, Schering and Johnson & Johnson (see GX-10d, GX-11c, 7/7/70 Govt. Prehearing Br.).

Third, bulk sales restrictions were not just inadvertently included in these agreements—it was the general policy of the defendants to include such restrictions in their agreements—indicating that the defendants intended the necessary consequences of their acts, and that the parties to such agreements were expected to and would comply therewith.

Furthermore, defendants considered such a restriction necessary, or they would not have imposed it. The fact that the parties considered it necessary to insert the illegal restriction into their agreements indicates the likelihood that its presence has had the desired effect of preventing offers to sell griseofulvin in bulk form to independent American drug companies and that its absence would have had the contrary effect.

Moreover, if these restrictive provisions are merely harmless sieves with no tendency to restrain competition, the defendants' past behavior would be irrational, which would be an implausible presumption. Thus, the fact that defendants have expended so much effort in obtaining these restrictive provisions and in attempting to uphold their validity in this case further indicates that the defendants expected them to and that they have had their intended anticompetitive effect, and that but for the restrictive provisions the bulk sales offers that the conspirators agreed to prevent would have, or would have been likely to have, been made.

The foregoing answer applies to all of the companies listed in the interrogatory. In addition, since this case was filed, AMHO (Ayerst Div.) has offered to resell bulk griseofulvin to several independent drug companies at about double the price it pays ICI for the product (see Govt. Prehearing Br., p. 9)—an unrealistic offer, because of the high price (as affidavits submitted with the Govt. Prehearing Br. show). Nevertheless, the fact of Ayerst's now making even an unrealistic offer, and only after ICI advised Ayerst that the latter need no longer comply with the illegal bulk sale restriction, tends to indicate the past effect of the restriction, and by the same token, to

indicate that but for the illegal restriction the restrained licensees, generally, and Ayerst in particular, would in the past have behaved differently from the way they unlawfully promised to.

/s/ RICHARD H. STERN

Dated: Aug. 3, 1970

EXHIBIT A, ANNEXED TO GOVERNMENT'S AUG. 3, 1970, ANSWER TO GLAXO'S INTERROGATORY

GLAXO GROUP LIMITED
47 PARK STREET, LONDON, W.1

20th June 1962.

Mr. J. H. Maynard,
Division Assistant Secretary,
I.C.I. Pharmaceuticals Division,
Fulshaw Hall,
Wilmslow,
Cheshire.

Dear Mr. Maynard,

re: *Griseofulvin*

Thank you for your letter of 18th June 1962. The draft you enclosed appears to reflect so little of the proposals I made in my letter to Mr. Bland of 2nd March 1962 that I feel compelled to invite you to reconsider the document and let me have your further comments.

Quite apart from there being no apparent financial return to Glaxo, the draft appears to extend Ayerst's franchise to the complete manufacture of griseofulvin and not merely the milling of standard to F. P. griseofulvin and to permit Ayerst to sell in bulk and not merely in the form of preparations. You will readily appreciate that if our understanding of its terms is correct, we cannot give the draft serious consideration.

Yours sincerely,

A. E. BIDE,
Company Secretary

APPENDIX A TO AFFIDAVIT OF THOMAS W.M. BLAND, DATED NOVEMBER 26, 1968

GRISEOFULVIN—U.S.A.

ESTIMATED SHARES (DOLLAR AMOUNT) OF GRISEOFULVIN MARKET (EXCLUDING SALES TO U.S. GOVERNMENT) 1965-1967

	1965	
	$000	%
Schering	2,993	53.4
McNeil (Johnson and Johnson)	1,568	28.0
American Home Products	1,045	18.6
Total:	5,606	100.0

	1966	
	$000	%
Schering	2,909	51.4
McNeil (Johnson and Johnson)	1,339	23.6
American Home Products	1,415	25.0
Total:	5,663	100.0

	1967	
	$000	%
Schering	3,291	55.1
McNeil (Johnson and Johnson)	1,553	26.0
American Home Products	1,127	18.9
Total:	5,971	100.0

APPENDIX B TO AFFIDAVIT OF THOMAS W.M. BLAND, DATED NOVEMBER 26, 1968

GRISEOFULVIN—U.S.A.

ESTIMATED SHARES (DOLLAR AMOUNT) OF TOTAL GRISEOFULVIN MARKET IN 1967

Excluding Sales to U.S. Government

	$000	%
Schering	3,291	55.1
McNeil (Johnson and Johnson)	1,553	26.0
American Home Products	1,127	18.9
Total:	5,971	100.0

Sales to U.S. Government

	$000	%
Schering	366	20.6
McNeil (Johnson and Johnson)	1,418	77.2
American Home Products	40	2.2
Total:	1,824	100.0

Total

	$000	%
Schering	3,657	46.9
McNeil (Johnson and Johnson)	2,971	38.1
American Home Products	1,167	15.0
Total:	7,795	100.0

AFFIDAVIT OF JEFFERSON B. HILL CONCERNING GRISEOFULVIN PRICES, DATED DECEMBER 15, 1970.

[Caption Omitted]

* * * * *

2. I have examined the six most recent annual editions of "Drug Topics Red Book," to ascertain the published price schedules for griseofulvin. The Drug Topics Red Book is a standard annual reference work prepared for pharmacists. It provides prices for drugs on the basis of information supplied to the publishers by the manufacturers of such drugs. The information tabulated below is the price to the retail druggist per 100 capsules or tablets, in the 250 mg. size. All prices in the Drug Topics Red Book set out below were listed on the basis of a quantity of 100 except for Schering, which does not sell microsize griseofulvin in that quantity. The price tabulated for Schering's microsize griseofulvin are 100]250's of the price for 250 units.

3. The following are prices, as indicated, for griseofulvin in the regular size:

Years	*Ayerst (AMHO)*	*McNeil (J&J)*	*Schering*
1971	$10.40	$10.40	$10.40
1970	$10.40	$10.40	$10.40
1969	$10.40	$10.40	$10.40
1968	$10.40	$10.40	$10.40
1967	$10.40	$10.40	$10.40
1966	$10.40	$10.40	$10.40

4. The following are prices, as indicated, for microsize griseofulvin:

Years	*Ayerst (AMHO)*	*McNeil (J&J)*	*Schering*
1971	$12.14	$12.10	$12.04
1970	$12.14	$12.10	$12.04
1969	$12.14	$12.10	$12.04
1968	$12.14	$12.10	$12.04
1967	$12.14	$12.10	$12.04
1966	250 mg. size not listed	$12.10	$12.04

/s/ Jefferson B. Hill

VERIFIED STATEMENT OF WALDEMAR A. HAHN, DATED DEC. 9, 1970

AMERICAN HOME PRODUCTS CORPORATION

Verified statement in lieu of documents in response to Paragraphs II-1 and II-2 of United States Subpoena duces tecum dated December 1, 1970

Pharmaceuticals sold or offered for sale in "Bulk Form" (as defined in the subpoena) in the United States by American Home Products Corporation and its divisions and subsidiaries (exclusive of any intercorporate sales between such divisions or subsidiaries) and the annual dollar volume of such sales in "Bulk Form" were as follows:

Year	*Product*	*Sales*
1960	Dibenzyl diacetate	$ 2,915.00
	Meperidine Hcl.	1,250.00
	Mercuzanthin Pwd.	550.00
	Penicillin Potassium G Crude	136,902.88
	Penicillin Potassium G Crys.	528.00
	Penicillin Procaine Cryst.	9,045.00
	Penicillin Procaine Micro.	1,755.00
1961	Dibenzyl diacetate	2,075.00
	Gas Gangrene	27,613.80
	Penicillin for animal feed	4,699.18
	Penicillin Potassium G crude	161,822.04
	Penicillin Potassium G Crys.	2,430.00
	Penicillin Procaine Benzathine Vet.	3,155.00
	Promazine Hcl	30,000.00
	Mephentermine	6,868.00
1962	Dibenzyl diacetate	1,380.50
	Gas Gangrene	30,173.70
	Mercuzanthin Pwd.	550.00
	Penicillin for animal feed	23,919.77
	Penicillin Potassium G Crude	223,053.52
	Chlorhexedine diacetate	975.00
1963	Dibenzyl Diacetate	$ 580.00
	Mercuzanthin Pwd.	108.40
	Penicillin for animal feed	6,530.22
	Penicillin Potassium G crude	169,775.46
	Mephentermine	1,700.00
	Chlorexedine Diacetate	18.75

Year	*Product*	*Sales*
1964	Dibenzyl Diacetate	2,304.50
	Meperidine Pwd.	4.80
	Penicillin for animal feed	7,954.39
	Penicillin Potassium G crude	170,575.72
	Promazine Hcl.	180.00
	Chlorhexedine Diacetate	225.00
1965	Penicillin-Benzathine	5,432.67
	Penicillin for animal feed	1,776.77
	Penicillin Potassium G crude	201,572.73
	Penicillin Procaine Cryst.	1,680.00
1966	Penicillin-Benzathine	2,915.49
	Penicillin for animal feed	6,361.11
	Penicillin Potassium G crude	29,356.34
	Chlorhexedine Diacetate	105.00
1967	Penicillin-Benzathine	4,559.50
	Penicillin Potassium G	110.00
	Promazine Hcl.	1,500.00
	Cetyltrimethyl ammonium bromide	75.00
1968	Promethazine Hcl.	1,500.00
	Sodium Nafcillin	2,250.00
	Sodium Nafcillin	3,750.00
	Griseofulvin	379.00
	Pregnant Mares' Serum Gonadotropin	585.00
1969	Dibenzylethylene	$ 562.50
	Ethel Cyclopentane	500.00
	Penicillin-Benzathine	5,699.01
	Sodium Nafcillin	2,500.00
1970*	Dibenzylethylene	115.00
	Meperidine Hydr.	17,000.00
	Nafcillin Monhy.	2,500.00
	Griseofulvin (microsized)	423.00

WALDEMAR A. HAHN, being duly sworn, deposes and says:

That he is Assistant Secretary of American Home Products Corporation;

That the foregoing statement was prepared from records of the corporation or its divisions or subsidiaries and that deponent is informed and believes that all matters therein stated are true.

/s/ Waldemar A. Hahn

* Through October 1970.

AFFIDAVIT OF DONALD R. DUNNER, DATED DECEMBER 16, 1970

[Caption Omitted]

1. I am an attorney retained by A. H. Robins Company, Richmond, Virginia, and am a member of the firm of Lane, Aitken, Dunner & Ziems, Washington, D.C. I have prepared this affidavit in response to a subpoena duces tecum addressed to said client.

2. The books and records of said client indicate the following annual purchases from Schering Corporation of chemicals in bulk form for pharmaceutical use, during the five most recent calendar years:

Year	*Pheniramine Maleate*		*Brompheniramine Maleate*	
	$ (nearest 1000)	*Kgm (nearest 100)*	*$ (nearest 100,000)*	*Kgm (nearest 1000)*
1969	0	0	300,000	4000
1968	0	0	400,000	4000
1967	3000	50	400,000	3000
1966	13000	200	400,000	3000
1965	59000	900	300,000	2000

/s/ Donald R. Dunner

AFFIDAVIT OF RICHARD J. BENNETT, DATED DECEMBER 15, 1970

[Caption Omitted]

RICHARD J. BENNETT, being duly sworn says:

I am Vice-President, Secretary and General Counsel of Schering Corporation.

Attached is a tabulation of the domestic sales by Schering Corporation, for the years since 1961, of bulk chemicals sold by it to others for pharmaceutical use.

/s/ Richard J. Bennett

Schering Corporation

BULK SUBSTANCE SALES
By Year 1961 Thru 6.30.70

	1.1.70-6.30.70		1969		1968		1967		1966	
	No. of Purchasers	*Amount*	*No. of Purchasers*	*Amount*	*No. of Purchasers*	*Amount*	*No. of Purchasers*	*Amount*	*No. of Purchasers*	*Amount*
Brompheniramine Maleate	1	$120,336	1	$ 412,000	1	$ 378,725	1	$ 340,750	1	$ 389,063
Aluminum Aspirin Carbinoxamine Maleate	4	115,175	4	151,350	4	119,875	5	59,039	4	42,513
Carbinoxamine D. Tartrate			1	6,132			1	7,494		
Chlorpheniramine Maleate	2	3,550	3	22,585	4	48,190	4	31,430	4	55,100
Fluphenazine Pheniramine Maleate	1	1,275	1	1,190	1	1,020	3	14,700	3	78,740
Sodium Thioglucose Trichloromethiazide	1	43,552	1	85,079	1	76,911	1	75,531	1	61,780
Hydroxy Progesterone Alcohol Perphenazine	1	486,000	1	1,404,000	1	1,734,750	1	924,750	1	1,397,250
Total		$769,888		$2,082,336		$2,359,471		$1,453,694		$2,024,446

BULK SUBSTANCE SALES—Continued
By Year 1961 Thru 6.30.70

	1965		1964		1963		1962		1961	
	No. of Purchasers	Amount	No. of Purchasers	Amount	No. of Purchasers	Amount	No. of Purchasers	Amount	No. of Purchasers	Amount
Brompheniramine Maleate	1	$309,238	1	$334,406	1	$235,350	1	$225,225	1	$167,700
Aluminum Aspirin					1	350			2	336
Carbinoxamine Maleate	5	54,148	4	47,170	5	49,500	5	22,710	5	31,617
Carbinoxamine D. Tartrate	1	6,875			1	11,190	1	13,615		
Chlorpheniramine Maleate	5	46,812	5	16,300	5	40,100	5	34,200	5	43,900
Fluphenazine	1	1,890			1	17,150	1	26,250	1	33,250
Pheniramine Maleate	5	118,044	6	128,344	9	134,191	12	141,491	16	98,784
Sodium Thioglucose					1	590	1	537		
Trichloromethiazide	1	60,465	1	46,781	1	26,441	1	29,940	1	11,900
Hydroxy Progesterone Alcohol			2	59,742	1	9,126				
Perphenazine	1	575,100			1	16,200				
Total		$1,172,572		$632,743		$540,188		$493,968		$387,487

AFFIDAVIT OF THOMAS A. SCHULZ, DATED DEC. 15, 1970, CONCERNING AMHO SUBPOENA RETURN

[Caption Omitted]

* * * * *

2. The documents attached hereto were submitted to the government by American Home Products Corporation in response to the subpoena duces tecum issued thereto by Order of this Court dated December 7, 1970.

/s/ Thomas A. Schulz

EXHIBIT 1A, ANNEXED TO SCHULZ AFFIDAVIT OF DECEMBER 15, 1970

AYERST LABORATORIES
DIVISION OF AMERICAN HOME PRODUCTS GORPORATION
685 Third Avenue, New York, N.Y. 10017

June 26, 1969

Mr. W. Hoffer, Senior Buyer
Chemicals & Raw Materials
Purchasing Department
Lederle Laboratories
Pearl River, New York 10965

Dear Mr. Hoffer:

We have reviewed our supply situation on both bulk and microsize griseofulvin and find that in consideration of our own requirements and commitments we have already made, we will be unable to supply you with the material you have requested.

Should there be any change in the supply situation in the future I will be in touch with you.

Very truly yours,
WILLIAM L. DAVIS

EXHIBIT 1B, ANNEXED TO SCHULZ AFFIDAVIT OF DECEMBER 15, 1970

LEDERLE LABORATORIES
A DIVISION OF AMERICAN CYANAMID COMPANY
PEARL RIVER, NEW YORK 10965

August 28, 1969

Ayerst Laboratories
Division of American Home
Products Corporation
685 Third Avenue
New York, New York 10017

Attention: Mr. William L. Davis

Gentlemen:

This will confirm our telephone conversation of August 28, 1969.

It is agreed that Ayerst will be in a position to furnish Lederle with up to 150 kilos per year of bulk Griseofulvin for use in topical products. It is understood that Ayerst will not be in a position to furnish Lederle with bulk or microsized Griseofulvin for use in capsules based on its own demands and commitments it has made to others.

This information is being passed on to our Marketing people so that they can proceed with their plans for the topical products.

Very truly yours,

A. T. Ericson
Manager, Administrative Services

EXHIBIT 1C, ANNEXED
TO SCHULZ AFFIDAVIT
OF DECEMBER 15, 1970.

Ayerst Laboratories
DIVISION OF AMERICAN HOME PRODUCTS CORPORATION
685 Third Avenue, New York, N.Y. 10017

September 16, 1969

Mr. A. T. Ericson
Manager, Administrative Services
Lederle Laboratories
Pearl River, New York 10965

Dear Mr. Ericson:

I am writing in response to your letter of August 28 to correct the impression which that letter erroneously presents. I want to make perfectly clear that Ayerst has no interest in restricting Lederle as to the use it makes of griseofulvin purchased from Ayerst. Indeed, Lederle's future use of griseofulvin is of interest to Ayerst only in so far as it gives us some insight as to the amount of griseofulvin Lederle might desire to purchase from us in the future.

As previously mentioned to you, we do not expect to be in a position to supply Lederle with the large quantities it would need for the marketing of griseofulvin capsules, but we do hope to be able to supply you with the more limited (150 kilos) quantities required for topical preparations. This is the sole reason for our interest in your future use

of griseofulvin and again any griseofulvin purchased from us may be used in any way Lederle thinks proper.
I trust this clarifies this matter.

Very truly yours,

WILLIAM L. DAVIS

EXHIBIT 2, ANNEXED
TO SCHULZ AFFIDAVIT
OF DECEMBER 15, 1970.

May 16, 1969

Mr. Harold Snyder, President
Biocraft Laboratories, Inc.
92 Route 16
East Paterson, New Jersey

Dear Mr. Snyder:

Your letter of May 9 to Mr. Goetchius of our organization has been referred to me. We are pleased to make the following quotations on bulk griseofulvin.

BULK GRISEOFULVIN

Quantities of 50 kilos—$123.00 per kilo
100 kilos— 120.00 per kilo
250 kilos— 117.00 per kilo

All prices are f.o.b. Rouses Point, New York, and the terms are net 10 days. It should also be specified that the quantity discount is applicable only when one shipment is made.

If you would like to have material to do some clinical studies we might be able to supply this to you, but we first have to know what quantity you will require. Even though the quantity would be less than 50 kilos these would be supplied at the 50 kilos price.

Also listed below are the prices for griseofulvin microsize capsules.

GRISEOFULVIN MICROSIZE CAPSULES

125 mg. potency at $25.15 per 1000 capsules
250 mg. potency at 46.30 per 1000 capsules

The minimum quantity order is 500,000 capsules of each potency, prices quoted are f.o.b. Rouses Point, New York and terms are net 10 days following the date of the invoice. The griseofulvin microsize capsules can only be supplied to you as a finished product. These will be supplied in bulk for packaging by you.

With respect to the availability, the situation does not look very promising at this point. We have many complaints now on our capabilities of producing so we really cannot hold out much hope for supplying you material until much later this year.

Orders for any form of griseofulvin must be submitted to us at least 90 days prior to the date of expected shipment. When your order is shipped you will resolve the necessary certification documents.

Since our ability to supply you is contingent upon the availability of raw material from our supplier, the prices quoted are subject to withdrawal at any time without prejudice to us.

Very truly yours,

WILLIAM L. DAVIS

EXHIBIT 3, ANNEXED
TO SCHULZ AFFIDAVIT
OF DECEMBER 15, 1970.

10:30 a.m.
April 28, 1969

[AMHO Memorandum]

Mr. Mason of Zenith Labs. called indicating an interest in placing an order for 250 mg. microsized griseofulvin capsules. I advised him that at this time we were not able to supply due to our own needs plus outside commitments.

He said he would take it on the 120 days rather than the 90 days as specified in my previous correspondence. I advised him that in all probability there would be no material available until much later this year.

He also asked for information about processing FDA forms. I told him I would obtain this information for him.

I also told him that I would let him know in 30 days if there was any change in our stock position.

EXHIBIT 4A, ANNEXED TO SCHULZ AFFIDAVIT OF DECEMBER 15, 1970.

AYERST LABORATORIES
Internal Correspondence

TO	Mr. W. L. Davis
FROM	Mr. F. R. Forbes
SUBJECT	
LOCATION	New York, New York
LOCATION	Rouses Point, New York
DATE	March 18, 1970 (Dict. March 17, 1970)

Dear Bill:

I had a call this afternoon from Dr. R. E. Lux of the Chromalloy American Corporation of Evansville, Indiana, with home offices in Missouri, concerning our ability to supply them with bulk Griseofulvin. Evidently there are two divisions of this company, one of them on the West Coast and another one whose name I did not catch.

Apparently they are desirous of marketing Griseofulvin. I indicated to Dr. Lux that I was not in a position to give him encouragement since we were having difficulty in obtaining sufficient bulk material ourselves from I.C.I. to meet our current demands. He seemed rather insistent that he get some answers, so I told him that he should write to you directly at 685 Third Avenue.

A review of our files reveals that on February 18 I received a similar request from Dr. Lux which was subsequently sent on to you under date of February 25.

Sincerely,

Frank

EXHIBIT 4B, ANNEXED TO SCHULZ AFFIDAVIT OF DECEMBER 15, 1970.

CHROMALLOY AMERICAN CORPORATION
P.O. BOX 6303 EVANSVILLE, INDIANA 47712

March 17, 1970

Mr. William Davis, Exec. VP
Ayerst Laboratories Inc.,
685 3rd Ave.,
New York, N.Y.

Dear Mr. Davis:

Chromalloy American Corporation have just completed arrangements with Imperial Chemical Industries for the licensing of griseofulvin. Two of our divisions, the Linden Pharmaceutical division and the Burns Pharmaceutical division are in the process of making plans to market the product.

We have been informed by Imperial Chemical Industries that Ayerst has been appointed as sole distributors and importers of substance.

On February 18 I wrote your Vice President for Manufacturing, Mr. F. R. Forbes at his request after speaking to him on the telephone. At that time he spoke of a "critical" supply situation. Not having heard from him in the interim I again called today. He suggested that I contact you.

We are anxious to proceed. We will therefore appreciate being advised as to when Ayerst should be in a position to supply the quantities delineated to Mr. Forbes in my letter of February 18.

Yours very truly,

RUSSELL LUX,
Vice President—Pharmaceutical Group

EXHIBIT 5A, ANNEXED
TO SCHULZ AFFIDAVIT
OF DECEMBER 15, 1970.

June 18, 1969

Mr. Philip Ritter III, President
Cole Pharmacal Company, Inc.
3721 Laclede Avenue
St. Louis, Missouri 63108

Dear Mr. Ritter:

Your letter to Mr. Johnson with regard to griseofulvin has been referred to me. We are pleased to make the following quotation on microsize griseofulvin capsules.

125 mg. potency at $25.15 per 1000 capsules
250 mg. potency at 46.30 per 1000 capsules

Microsize griseofulvin can only be supplied to you in finished dosage form. The prices quoted are in bulk for packaging by you. The minimum quantity per order is 500,000 capsules of each potency, prices quoted are f.o.b. Rouses Point, New York and terms are net 10 days following the date of invoice. Orders for microsize griseofulvin must be submitted to us 120 days prior to the date of expected shipment.

Because of a rather severe shortage of raw material there is some question about the future availability. Since our ability to supply you is contingent upon the availability of raw material from our supplier, the prices quoted are subject to withdrawal at any time without prejudice to us.

Very truly yours,
WILLIAM L. DAVIS

EXHIBIT 5B, ANNEXED
TO SCHULZ AFFIDAVIT
OF DECEMBER 15, 1970

July 25, 1969

Mr. Philip Ritter III
Cole Pharmacal Company, Inc.
372 Laclede Avenue
St. Louis, Missouri 63108

Dear Mr. Ritter:

Since receiving your letter of July 1, I have re-examined our position on Griseofulvin and find it has actually worsened. We have several commitments for supplying finished

products to other firms and that along with our own demands makes it impossible to accept any more orders at this time.

Your assumption that this will arrive to you with batch certification is correct. The FDA would want to re-check your finished package since it will only be certified, finished and packaged by us in bulk.

Very truly yours,
WILLIAM L. DAVIS

EXHIBIT 5C, ANNEXED TO SCHULZ AFFIDAVIT OF DECEMBER 15, 1970

COLE PHARMACAL COMPANY, INC.
3721 LACLEDE AVENUE ST. LOUIS, MISSOURI 53108

July 1, 1969

Mr. William L. Davis
Vice President, Marketing
Averst Laboratories
685 Third Avenue
New York, New York 10017

Dear Mr. Davis:

Thank you very much for your letter and quotation on microsize griseofulvin of June 18.

I have made note of the fact that there is a 120 day lead time, a minimum quantity per order of one half million capsules and that there is some question in your mind as to your continuing ability to supply us. Prior to moving ahead I wonder if you could shed some light on this latter point? In the event of your possible inability to supply, would there be, or is there, a secondary source? I am sure you understand the rather awkward circumstance it would develop should we, having marketed the product, be then in the course of the year unable to fill our orders.

Since the product would be coming to us in finished dosage form I hope I am correct in assuming that the batch certification would have been made by the FDA.

I would appreciate your comment on these several points.

Sincerely,
PHILIP RITTER III

EXHIBIT 6, ANNEXED
TO SCHULZ AFFIDAVIT
OF DECEMBER 15, 1970

February 6, 1970

Mr. Sidney Rich, President
Phoenix Laboratories, Inc.
119 Bloomingdale Road
Hicksville, New York 11801

Dear Mr. Rich:

I have been asked by our President, Mr. C. M. Johnson, to reply to your letter of January 22 regarding the availability of Griseofulvin.

I am sorry to say that due to the lack of sufficient quantities of bulk Griseofulvin, we will be unable to handle your request at this time.

We will be pleased to give your request for Griseofulvin further consideration in another six months or so providing the supply situation has improved.

Sincerely yours,
WILLIAM L. DAVIS

EXHIBIT 7, ANNEXED
TO SCHULZ AFFIDAVIT
OF DECEMBER 15, 1970

February 13, 1969

Owen Laboratories Incorporated
8911 Directors Row
Dallas, Texas 75247
Attention of Arvon J. Jones, Vice-President

Dear Mr. Jones:

With reference to your inquiry on griseofulvin (microsize) capsules, we are willing to sell to you griseofulvin (microsize) capsules, 125 mg. potency at $25.15 per 1000 capsules and 250 mg. potency at $46.30 per 1000 capsules. Prices quoted are f.o.b. Rouses Point, New York, minimum quantity order 500,000 capsules for each potency. Terms are net, 10 days following date of invoice.

Capsules will be imprinted with your tradename "Owen" or such other lettering as you desire. Color of capsules will

be in accordance with your specification, provided it is not the same as or similar to that used by Ayerst.
I should emphasize that our ability to supply you as aforesaid is subject to the availability to us of raw material. Therefore, you will understand that this offer may be withdrawn by us at any time without prejudice to us.
I would further advise that you should allow at least three months for delivery following receipt by us of your order.
We look forward to hearing from you.

Very truly yours,
MAURICE E. SILVERSTEIN

EXHIBIT 8, ANNEXED
TO SCHULZ AFFIDAVIT
OF DECEMBER 15, 1970

February 26, 1969

Mr. S. George Greene
President
West-ward, Incorporated
74 Maple Avenue
Bronx, New York 10416

Dear Mr. Greene:

In response to your letter of February 21, I am pleased to give you the following quotation on griseofulvin (microsize) capsules.
We will supply you with griseofulvin (microsize) capsules:

125 mg. potency at $25.15 per 1000 capsules.
250 mg. potency at $46.30 per 1000 capsules.

The minimum quantity order is 500,000 capsules of each potency, prices quoted are f.o.b. our plant in Rouses Point, New York, terms are net ten days following the date of the invoice.
I am sure that your letter requested raw material, but we are only permitted to supply you the finished product and, as stated, these will be suplied in bulk for packaging by you.
I should emphasize that our ability to supply you as mentioned is subject to the availability of raw material to us.

Therefore, you will understand that this offer may be withdrawn by us at any time without prejudice to us.
I would further advise that you should allow at least three months for delivery following receipt by us of your order.
I look forward to hearing from you.

Sincerely,
WILLIAM L. DAVIS

EXHIBIT 9, ANNEXED
TO SCHULZ AFFIDAVIT
OF DECEMBER 15, 1970

March 23, 1970

Dr. Russell E. Lux
Vice President
Chromalloy American Corporation
P.O. Box 6303
Evansville, Indiana 47712

Dear Dr. Lux:

With reference to your recent letter to Mr. F. R. Forbes requesting information on griseofulvin (microsize), I am pleased to offer to you the following quotation:

125 mg. potency at $26.15 per 1,000 capsules
250 mg. potency at $46.30 per 1,000 capsules

Prices quoted above are in bulk for packaging by you. Color of capsules will be as specified by you provided such colors are not the same as, or confusingly similar to that used by Ayerst. Minimum quantity per order is 500,000 capsules of any potency.

If you should desire griseofulvin (microsize) in bulk, prices are as follows:

Quantity	Price
25- 99 kilograms per shipment	$141 per kilogram
100-249 kilograms per shipment	$138 per kilogram
250 kilograms and over per shipment	$135 per kilogram
Minimum order—25 kilograms	

All prices quoted herein are F.O.B. our plant Rouses Point, New York and terms are net 10 days following date of invoice. All orders, should be addressed to the undersigned,

must be submitted at least three months prior to date of requested delivery.
I must emphasize that because our ability to supply you is contingent upon the availability of raw material from our supplier, all prices quoted herein are subject to withdrawal at any time without prejudice to us. Finally, we must be assured that you have complied with the requirements of the Federal Food & Drug Act and regulations thereunder prior to our shipment to you.
I look forward to hearing from you.

Sincerely,
WILLIAM L. DAVIS

EXHIBIT 10, ANNEXED TO SCHULZ AFFIDAVIT OF DECEMBER 15, 1970

March 31, 1970

Mr. Jack Laub
Vice President
Wolins
75 Marcus Drive
Melville, New York 11746

Dear Mr. Laub:

In response to your telephone request of March 30, I am submitting to you the prices on griseofulvin (microsize) bulk.

Quantity	Price
25-99 kilograms per shipment	$141 per kilogram
100-249 kilograms per shipment	$138 per kilogram
250 kilograms and over per shipment	$135 per kilogram
Minimum order—25 kilograms	

All prices quoted herein are F.O.B. our plant Rouses Point, New York and terms are Net 10 days following date of invoice. All orders which should be addressed to the undersigned, must be submitted at least three months prior to date of requested delivery.

I must emphasize that because our ability to supply you is contingent upon the availability of raw material from our supplier, all prices quoted herein are subject to withdrawal at any time without prejudice to us. Finally, we must be assured that you have complied with the requirements of the Federal Food & Drug Act and regulations thereunder prior to our shipment to you.

I look forward to hearing from you.

Sincerely,
WILLIAM L. DAVIS

EXHIBIT 11, ANNEXED TO SCHULZ AFFIDAVIT OF DECEMBER 15, 1970

October 2, 1970

Mr. Robert Mazon
Zenith Laboratories Inc.
150 South Dean Street
Englewood, New Jersey 07631

Dear Mr. Mazon:

This is in reference to our telephone conversation this past week in which you informed me of the possibility of your ordering an additional 500,000 griseofulvin capsules (microsize), 250 mg. potency.

As I have previously informed you, our price for the 250 mg. potency is $46.30 per 1,000 capsules. The minimum quantity order is 500,000 capsules. Because of some confusion in payment in connection with your last order, I should emphasize to you that our terms are f.o.b. Rouses Point, New York, *net 10 days following date of invoice.* All orders should be addressed to me and must be submitted at least three months prior to date of requested delivery. As indicated to you in connection with your previous order, our ability to supply you is contingent upon the availability of raw material from our supplier; all prices quoted herein are subject to withdrawal at any time without prejudice to us.

I look forward to hearing from you.

Sincerely,
MAURICE E. SILVERSTEIN

cc: W. L. Davis
J. G. Faherty

FINAL JUDGMENT PROPOSED BY UNITED STATES [SERVED MAY 20, 1970]

[Caption Omitted]

* * * * *

IV.

* * * * *

(C) For as long as Glaxo makes or offers to make United States sales of griseofulvin, but not to exceed ten years from the date of entry of this Final Judgment, Glaxo is ordered to sell, on reasonable and nondiscriminatory terms and prices, such product to any applicant therefor in the United States.

(D) Glaxo is further ordered to grant each applicant therefor a nonexclusive, unrestricted license, upon reasonable and nondiscriminatory terms and royalty rates, on any or all United States patents (existing at the time of entry of this Final Judgment or issued within five years from such date of entry), and technical data which at present or at any time during the five years following the date of entry of this Final Judgment, Glaxo owns or has any power to license, which patents and data are used or usable for making, processing or using griseofulvin.

(E) For as long as ICI makes or offers to make United States sales of griseofulvin, but not to exceed ten years from the date of entry of this Final Judgment, ICI is ordered to sell, on reasonable and nondiscriminatory terms and prices, such product to any applicant therefor in the United States.

(F) ICI is further ordered to grant each applicant therefor a nonexclusive, unrestricted license, upon reasonable and nondiscriminatory terms and royalty rates, on any or all United States patents (existing at the time of entry of this Final Judgment or issued within five years from such date of entry), and technical data which at present or at any time during the five years following the date of entry of this Final Judgment, ICI owns or has any power to license, which patents and data are used or usable for making, processing or using griseofulvin.

* * * * *

V.

(A) Upon receipt of written application for a license under Section IV above, defendant (Glaxo or ICI, as the case may be) shall advise the applicant in writing within 30 days of the royalties which such defendant deems reasonable for the patent(s) or technical data to which the requests pertains. If the applicant rejects the royalties proposed by such defendant, and if such defendant and applicant are unable to agree upon reasonable royalties within 60 days from the date such rejection is communicated in writing to defendant, the applicant or defendant may, upon notice to the plaintiff, applying to this Court for the determination of (1) reasonable royalties and (2) such reasonable interim royalties (pending the completion of any such proceeding) as toward Court may deem appropriate. In any such proceeding, the burden of proof shall be on defendant to establish the reasonableness of the royalties requested by it. Pending the completion of negotiations or any such proceedings, the applicant shall have the right to make, have made, use and vend under the patents and technical data to which his application pertains, subject to the payment of reasonable interim royalties shall be applicable to the applicant from the date upon which the applicant requested such license, and after such determination, unless otherwise ordered by the Court in the proceedings instituted under this Section V., be applicable to any other licensee then having or thereafter obtaining the same rights under the same patents or technical data. If the applicant fails to accept the license, such applicant shall pay the royalties found by the Court to be due to defendant and such costs as the Court may determine to be just and reasonable.

(B) Nothing herein shall prevent any applicant from attacking, in the aforesaid proceeding or in any other controversy, the validity or scope of any patent or patents nor shall this Final Judgment be construed as imputing any validity or value to any of said patents.

(C) Each defendant is enjoined from taking or accepting any right or license subject to any term or condition that would prevent such defendant from complying with the provisions of this Final Judgment, and from making any sale or other disposition of any patent, right or license which deprives it of the power or authority to grant licenses

in accordance with the provisions of this Final Judgment, unless the purchaser, transferee or assignee shall file with this Court, prior to the consumation of said transaction, an undertaking to be bound by its provisions.

NOTICE OF MOTION AND MOTION BY UNITED STATES FOR PARTIAL SUMMARY JUDGMENT AGAINST ICI ON RESTRAINT ON ALIENATION ISSUE PURSUANT TO RULE 56(d), FED.R.CIV.P., DATED OCT. 31, 1968

[Captions Omitted]

Plaintiff, United States of America, respectfully moves this Court for partial summary judgment against defendant ICI, declaring that ICI violated the Sherman Act (15 U.S.C. § 1) by imposing a restraint on alienation. The grounds for this motion, as set out more fully in the accompanying memorandum of points and authorities, are that ICI committed a *per se* illegal restraint of trade when it agreed with its vendee AMHO that such vendee would not sell to others bulk-form griseofulvin that ICI sold it.

CONCISE STATEMENT OF UNDISPUTED FACTS AND GENUINE ISSUES FILED UNDER LOCAL RULE 9(h), DATED OCT. 30, 1968 [#1]

[Caption Omitted]

I.

1. In 1957 defendants Glaxo and ICI agreed to pool certain patent rights relating to the manufacture and use of the drug griseofulvin.

2. The defendants further agreed that ICI would not permit ICI's vendees of griseofulvin to resell such drug in bulk.

3. In 1962 ICI agreed to sell griseofulvin in bulk to AMHO. AMHO agreed not to resell the drug in bulk, and instead to distribute it only in the form of pills or other dosage form products. Such products were to consist of griseofulvin and therapeutically inactive ingredients.

4. Since such date ICI has sold substantial amounts of

griseofulvin in bulk to AMHO. AMHO has sold substantial amounts of griseofulvin, in dosage form only, to others.

5. Since 1962 and up to the filing of this complaint, ICI and AMHO have each declined to sell griseofulvin in bulk form to third parties located in the United States, and have not done so.

II.

The only genuine issue presented in this motion is whether ICI's imposition on its vendee AMHO of a restraint on the alienation of griseofulvin is illegal under Section 1 of the Sherman Act (15 U.S.C. Section 1).

CONCISE STATEMENT OF UNDISPUTED FACTS AND GENUINE ISSUES FILED UNDER LOCAL RULE 9(h), OCT. 30, 1968 [#2]

[Caption Omitted]

I.

1. Defendant ICI owns United States Patent No. 2,900,304 ("Imperial patent").

2. The Imperial patent claims the method of curing fungus diseases by administering "effective amounts" of griseofulvin.

3. The Imperial patent does not disclose what amount constitutes an "effective amount" or any other information about the amount of dosage, duration of treatments or the types of fungus diseases which can be cured by such method.

4. The Imperial patent also claims griseofulvin, concededly an old substance, in the form of tablets and other dosage forms.

II.

The only genuine issues presented in this motion are whether a United States patent is valid which claims:

(a) A method of curing external fungus diseases by administering "effective amounts" of an old substance, without disclosing what amount constitutes an "effective

amount" or any other information about the amount or duration of dosage or the types of external fungus diseases which can be cured;

(b) As a product, an old antifungal substance in the form of pills or the like.

MEMORANDUM OF UNITED STATES IN REPLY TO JANUARY 16, 1968, MEMORANDUM OF ICI IN OPPOSITION TO PLAINTIFF'S MOTION TO AMEND, ETC. (JURISDICTION ISSUE), DATED JAN. 22, 1969

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, PLAINTIFF, v. GLAXO GROUP LIMITED AND IMPERIAL CHEMICAL INDUSTRIES LIMITED, DEFENDANTS.	Civil Action No. 558-68

Defendant ICI challenges the jurisdiction of this Court over the government's suit for a declaration that ICI's patent (hereafter referred to as the "Imperial patent") is invalid. ICI concedes (ICI January 16 memo, p. 12) that the government "has unquestioned authority" to bring such suits to rid the public of the burden of patents that are invalid because the patentee procured them by fraud, but ICI claims that the government is helpless to protect the public from any other specious patent monopoly. As we show below, ICI erroneously states the holdings in the cases that the government relies on and ICI's position is rejected in the very case on which it places principal reliance (the *Second Telephone* case).

I. BOTH THE *FIRST* AND *SECOND TELEPHONE* CASES PERMIT THE GOVERNMENT TO SUE TO ELIMINATE INVALID PATENTS, NOT ONLY WHEN PATENTS WERE PROCURED BY FRAUD BUT WHEN THERE WAS NO POWER TO GRANT THEM.

The decision of the Supreme Court makes it clear that fraud is not the only basis for the sovereign's taking away a patent that it granted. As the Court said in the *First Telephone* decision (*United States* v. *American Bell Telephone Co.*, 128 U.S. 315, 365 (1888)), "Nor is fraud in the patentee the only ground . . . . Patents are sometimes issued inadvisedly or by mistake, where the officer has no authority in law to grant them . . ." The Court went on to decide that the patent grant on the telephone had "taken from the public rights of immense value and bestowed them on the patentee" (*id.*, at 370). The importance to the public of whether the monopoly should have been granted was held to confer, by necessity and in the absence of any special statute, jurisdiction on the district court to determine the question; the Court therefore reversed the district court's grant of the patentee's motion to dismiss.

On remand, the government elected to try the case on the theory of fraudulent procurement (see *United States* v. *American Telephone Co.*, 167 U.S. 224, 227 (1897). On the second appeal the Court held that the government's evidence of fraud was inadequate and that it had failed to prove its case. In commenting on the law of the case and its own prior decision, the Court said (167 U.S., at 269; the passage quoted in ICI's January 16 memo, p. 3, and on which it principally relies) that the *First Telephone* decision—

> *rightfully affirmed the power of the government to proceed* by suit in equity against one who had wrongfully obtained a patent . . . for an invention . . . [by] fraud, or deceit, or mistake, or . . . *error as to power* . . . [Emphasis supplied.]

The *Second Telephone* decision then went on to observe that either fraud or deceit or mistake or error as to power to grant the patent was a proper basis for a suit to eliminate an invalid patent, but that "the mere ground of *error of judgment* on the part of the patent officials" was not (*ibid.*) (emphasis added).

It is clear from examination of the original complaint (¶ 20) in this case, the corresponding part of the amended complaint (¶ 12), and the government's motion for summary judgment of the invalidity of the Imperial patent (Oct. 30, 1968) that *total lack of statutory power* to grant the kind of patent issued is the basis for the government's challenge to ICI's claims on griseofulvin as a product. ICI claimed the concededly old and well known product griseofulvin in "pill" form. The government has urged in its complaint and motion for summary judgment on the point that the statute absolutely forbids the grant of "product" claims on previously known products and permits only "method" claims (see Govt. Oct. 30 memo, pp. 8-10). The merits of our contentions on this score are not at this time before the Court for decision, but the fact that this aspect of our case is based on such contentions brings the case at bar squarely within the rule stated in the *Second Telephone* case, on which ICI most places its reliance. As we show below, other decisions establish that the proper rule is even broader in scope than that stated (in dictum) in the *Second Telephone* case; but even under that narrow statement of the rule the government has stated a proper claim for relief as to invalidity of the product claims.

Accordingly, even if the *obiter dictum* in the *Second Telephone* case were deemed controlling, the present controversy is within the class of cases (fraud, deceit, mistake, *or error as to power*) expressly singled out as appropriate for government suit to relieve the public from an improperly granted patent. We turn now to the other cases that establish a broad power of the sovereign to institute suit to protect and enforce the public policy of the United States—a policy which calls for the judicial invalidation of specious patents and the elimination of spurious assertions of monopoly power based on such patents, irrespective of whether the patent was fraudulently procured.

II. THE ATTORNEY GENERAL HAS THE INHERENT POWER, BY VIRTUE OF HIS OFFICE, TO BRING THIS SUIT AND THE COURT HAS INHERENT POWER TO DECIDE IT.

A. *The Public Policy of the United States Requires Invalidation of Specious Patents to Protect Commerce and the Public from Unjustified Monopolies.*

It is just as much the public policy of the United States

that the public should not be burdened with a monopoly based on an invalid patent as it is that the discoverer of a true invention should be rewarded with a statutory monopoly. In dozens of cases, the Supreme Court has said that the policy of Article I, § 8 of the Constitution and the policy of the patent laws require that no monopolies be allowed on innovations or technical advances that do not rise to the Constitutionally dictated level of invention. See, e.g., *Graham* v. *John Deere Co.*, 383 U.S. 1, 5-6 (1966); *Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225, 230-231 (1964).

The Court has also made it clear that public policy favors the invalidation of specious patents to rid the public of their burden on commerce. This policy was articulated by the Supreme Court at least as early as *Pope Mfg. Co.* v. *Gormully*, 144 U.S. 224, 234 (1892), where the Court stated that "it is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly . . . ." Contrary to ICI's contention (ICI Jan. 16 memo, p. 8), *Pope* v. *Gormully* was not a case in which a patent was said to justify an otherwise illegal price fixing scheme; indeed, the Sherman Act was not even involved in the decision. On the contrary, the decision concerned whether it was against public policy to agree not to challenge the validity of patents. The Court ruled that public policy favored the challenge of invalid patents, because their elimination would protect the public from an improper burden, and that an agreement not to contest patent validity was against public policy.

Similarly, in the part of the passage from *Sinclair & Carroll Co.* v. *Interchemical Corp.*, 325 U.S. 327, 330 (1945), that is *not* quoted in defendant's brief (ICI Jan. 16 memo, p. 8), the Court said that the determination of patent invalidity should be made by lower courts, even though the particular case before them could be disposed of on other grounds, because the question of patent "validity has the greater public importance." In short, the Supreme Court directed the lower federal courts to reach issues not necessary for the disposition of the case, because it was more important to the public to have invalid patents removed from the rolls than it was to have the trial court dispose of a case on the narrow basis of the particular facts presented.

Such policies are summed up in the opinion of Justice White in *United States* v. *Singer Mfg. Co.*, 374 U.S. 174, 197-200 (1963) (concurring). Justice White did *not* assert what ICI attributes to him (ICI Jan. 16 memo, p. 8). To the contrary, he summarized a long line of authority on the public policy of the patent system to reach the conclusion (irrespective of fraud) that the public is imposed upon when a patent issues on something short of a true invention; if the public gets less than its *quid pro quo* for the monopoly, it is not a fair deal and the courts should take away the patent, not because of fraud but because of mere failure of consideration. He therefore concluded that "public policy favors the exposure of invalid patent monopolies before the courts in order to free the public of their effects.

We therefore think it clear that, if the Imperial patent is invalid then it is contrary to the Constitutional and statutory public policy of the United States to allow that patent to continue to masquerade on the books as valid. (In the present posture of the case (the question of jurisdiction or of failure to state a claim for relief), it must be assumed, *arguendo*, that the patent is indeed invalid.) We turn now to the further proposition that, given the federal policy that the invalid patent should not be allowed to continue as an obstruction to commerce (a sunken barge, so to say, in the stream of commerce), or that it is a kind of public nuisance—then the Attorney General of the United States has inherent authority to sue for judicial relief to protect and vindicate the applicable federal policy and to abate the nuisance.

B. *The Cases Recognize an Inherent Equity Jurisdiction over Suits Brought by the Attorney General to Protect the Federal Public Interest.*

ICI has sought to make the point that no statute expressly confers jurisdiction on the United States District Courts to entertain suits by the sovereign to declare patents invalid or to enjoin patentees from enforcing invalid patents.[1] That is, ICI claims a kind of sovereign immunity in reverse.

The federal courts have long recognized their inherent equity jurisdiction over suits brought by the Attorney

[1] For the reasons set forth below, it is unnecessary to reach the question of whether the instant suit is within the general ambit of such statutes as 28 U.S.C. § 1331, § 1345, or § 2201.

General of the United States to vindicate or protect the public interest in "federal question" matters. The *First* and *Second Telephone* cases are examples of such equity jurisdiction.

Similarly, in *United States* v. *San Jacinto Tin Co.*, 125 U.S. 273 (1888), the Attorney General sued to set aside a land patent but was challenged for alleged lack of statutory authority to bring such suits. The Supreme Court held that no statute was necessary for the Attorney General to sue on behalf of the United States "to set aside and declare void an instrument [land patent] issued under its apparent authority" (*id.*, at 279). ICI asks this Court to ignore the *San Jacinto* decision because there the patent was procured by fraud, unlike the ICI patent (ICI Jan. 16 memo, p. 4). But fraud had nothing to do with whether an express statute was required before the district court could have jurisdiction over the case.[2] Later Supreme Court decisions cite *San Jacinto* for the rule that the Attorney General has inherent authority to sue on behalf of the United States, and that the federal courts have inherent authority to entertain such suits, in a wide variety of "federal question" contexts *not involving fraud*.

For example, in *Sanitary District* v. *United States*, 266 U.S. 405 (1925), the government sued to compel Chicago to stop taking water out of Lake Michigan. On the jurisdictional issue raised here by ICI, the Supreme Court held: "The Attorney General by virtue of his office may bring this proceeding and no statute is necessary to authorize this suit" (*id.*, at 426, Holmes, J.). Again, in *United States* v. *Republic Steel Corp.*, 362 U.S. 482 (1960), the Court relied on *San Jacinto* as authority for a suit by the government to compel a factory to stop putting chemical wastes into a

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[2] ICI also seeks to distinguish *San Jacinto* on the theory that land patents are more important to the sovereign than patent monopolies based on alleged inventions. ICI urges that the United States parts "with nothing" in a patent on an invention (Jan. 16 memo, p. 4).

But as the Supreme Court noted in the *First Telephone* case, the public parts with rights of immense value. In the present case, the public has parted with (and, the complaint alleges, was improperly deprived of) the exclusive right to make, use, and sell, for 17 years, an important antibiotic with present annual U. S. sales (wholesale prices, about half of the retail price level) of nearly $8 million, $1.8 million of which was sold directly to plaintiff. For plaintiff to pay a monopoly price on $1.8 million worth of public domain drugs—while the rest of the public is muleted on another $6 million—is hardly to part "with nothing," we submit.

river, despite failure of the applicable statute to authorize injunctions.[3] The Supreme Court said (*id.*, at 492) that "the test was whether the United States had an interest to protect or defend." If there was a public interest, such as the maintenance of the level of Lake Michigan or keeping chemical wastes out of a river, the Court held, the Attorney General could properly sue (*ibid.*).

In the present case, the United States has an interest to protect—its interest in keeping commerce in drugs free of tollgates that are not authorized by the patent laws. As the Supreme Court held in *San Jacinto* and *Republic Steel*, the Attorney General "by virtue of his office" may therefore sue for an injunction to protect that interest.

ICI's contentions are completely put to rest by a decision handed down by the Supreme Court barely a year ago—*Wyandotte Co.* v. *United States*, 389 U.S. 191 (1967). In that case, the Court upheld the inherent power of the government to bring, and the jurisdiction of the courts to entertain, both suits for declaratory judgments and suits for financial reimbursement against conduct which interfered with commerce—even though the only applicable statute failed to provide for such declarations or reimbursements and conferred on the courts no jurisdiction to grant such relief. The Court said (*id.*, at 201) that the broad rule on such jurisdiction is: "Our decisions have established, too, the general rule that the United States may sue to protect its interests. [Citing *San Jacinto*, *Sanitary District*.]"

The *Wyandotte* decision involved two consolidated cases —*Cargill* and *Wyandotte*. In *Cargill*, the government sought a declaratory judgment that the owners of two barges which were negligently sunk were responsible for removing them from the Mississippi River. In *Wyandotte*,

[3] See also *United States* v. *Debs*, 158 U.S. 564 (1895), where the *San Jacinto* doctrine was invoked as the jurisdictional basis for a suit to enjoin interference with the federal mails. ICI asserts that the case was "unique" (Jan. 16 memo., p. 8), but ICI does not explain why the Court's ruling on jurisdiction there is appropriately to be restricted to the facts of the case. The uniqueness of the facts, if any, had to do with the substantive issue of whether an injunction should be granted—not with the question of whether the Court should entertain the suit in the absence of a statute. That there is nothing "unique" about *Debs* is shown by its recent citation by the Supreme Court for the rule that the sovereign has the general responsibility to keep the "routes of commerce . . . free of obstruction"—in the case there in issue, free of a sunken barge. See *Wyandotte Co.* v. *United States*, 389 U.S. 191, 201 (1967).

the government sought to recover its expenses in removing a sunken barge and its cargo, from the persons whose negligence has caused the sinking. In both instances, the Supreme Court found jurisdiction despite absence of a specific statute.[4] The Act made it unlawful to sink a vessel negligently, but it provided no remedies or duties other than that the party sinking the vessel should supply buoys and lanterns to mark the wreck. To the Court it was clear that Congress could not have "intended to withhold from the government a remedy that ensures the full effectiveness of the Act" (*id.*, at 204). It therefore held that the statutory remedies and duties were not exclusive and that other appropriate remedies, including the declaratory judgment that the government sought, were available by necessary implication.

By the same token, in the present situation the courts have already sustained, by necessary implication, the jurisdiction to grant the remedy that the government sought and secured in *Wyandotte* as to fraudulently procured patents and those patents issued by reason of error as to power to do so (also those patents issued by mistake or through deceit; see *Second Telephone* case, *supra.*). The product claims of the Imperial patent, as we have already shown above, fall within the long established rule because there is no *power* to issue the kind of patent here granted. The challenge to ICI's method claims, however, as the complaint and our motion for summary judgment on the issue reveal, is based on ICI's insufficient disclosure of the method; that is, the government contends that ICI did not comply with the requirements of the patent statute (35 U.S.C. § 112) by setting forth the manner to practice its alleged invention. (Again the substantive merits of the contentions are not now in issue and we must assume, *arguendo*, in the present posture of the case, the government is right on the merits.)

It requires no step beyond the existing cases—such as *San Jacinto, Sanitary District, Republic Steel, and Wyandott*—to find jurisdiction to declare whether or not ICI's

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[4] The Court does not refer to the Declaratory Judgments Act (28 U.S.C. § 2201), a statutory basis for the declaratory judgments sought in *Wyandotte* and the present case, but which need not be reached because of the settled line of "inherent authority" cases rested on *San Jacinto* and its progeny. Similarly, statutory jurisdiction could be based on 28 U.S.C. § 1331 (federal question) or 28 U.S.C. 1345 (suits where United States is plaintiff), but it is unnecessary to consider such matters, in view of the case law cited previously.

method claims are invalid. There is an interest of the United States involved and the Attorney General, by virtue of his office, seeks to have the Court determine it. No statute is necessary for that purpose, as the Supreme Court has repeatedly said. The dictum in the *Second Telephone* case that there are four situations (fraud, deceit, mistake, error as to power) can no longer, if it ever could be regarded as an all-inclusive enumeration. The sweep and logic of the later Supreme Court cases go far beyond the four categories mentioned in the *Second Telephone* case. They make it clear that the Attorney General, "by virtue of his office," may bring this suit to protect and enforce the policy of the patent laws and Constitution.

C. *It is Particularly Important, in the Present Antitrust Violation Context, That the Attorney General be Permitted to Assert the Public's Interest.*

ICI has sought to distinguish the *Gypsum* decision (*United States* v. *United States Gypsum Co.*, 333 U.S. 364 (1948) on the theory that *Gypsum* supports government challenge to patent validity only when the patentee asserts the patent in defense of an otherwise illegal practice. We submit that *Gypsum* should be understood more broadly to support challenge to any patent used by antitrust defendants in furtherance of their illegal program. The importance of the Imperial patent to the defendants' scheme to violate the antitrust laws is plain. It was, according to ICI's contentions, the reason for the patent pool agreement in the first place; Glaxo's grant of rights to ICI was paid for with the Imperial patent. Without the Imperial patent the defendants could not maintain their monopoly in the United States over the drug, for then anyone who could secure bulk form griseofulvin could make it up into pills and sell them without a patent to stop him; bulk form griseofulvin is, as ICI points out, unpatented. The Imperial patent thus bolsters the effectiveness of the illegal restraint on alienation ICI imposes on the resale of bulk form griseofulvin: if a small drug company somehow manages to get the unpatented bulk form drug despite ICI's restraint on alienation designed to prevent it or anyone else from doing so, the defendants may still suppress the manufacture of the drug by threat of patent infringement suit. In this context, vindication of the public interest in competition in

unpatentable goods is doubly important—for there is a double impediment to commerce—the patent and the conspiracy.

To be sure, it may be that private parties might challenge the Imperial patent's validity, in the absence of action by the Attorney General. If they did so, they might well vindicate the public interest in keeping the public from paying monopoly tolls to a spurious patent, assuming that their investigative and prosecutorial resources were adequate (this is, to say the least, a questionable assumption). But the probability of any such persons acting on the public's behalf, to relieve the public of the burden of an improper monopoly is very slight in the present case: ICI has teamed up with its competitor Glaxo in a patent pool, and each has agreed not to challenge the other's patents or to permit any associate or independent third party licensed by them to do so (GX-3, pp. 12-13, ¶ 9(a), annexed to Govt. October 31, 1968, motion for summary judgment on restraint on alienation issue). ICI has entered into an exclusive dealing agreement with its licensee AMHO, eliminating its incentive to challenge the patent; and its partner Glaxo has brought Schering and J&J, the other two established sellers, into the arrangement, enlisting their support in maintaining the monopoly.

The upshot is that the private parties most likely or most able to challenge the patent have all been enlisted in the defendants' program. Considering the cost of patent litigation to any would-be entrant into this somewhat limited market (less than $10 million total wholesale sales per year at present), measured along with the chances of diverting a substantial share of the market from the established firms, it would not appear probable that "private attorneys general" will sue ICI to vindicate the public interest in the integrity of the patent system. In the circumstances, it is particularly important that the Attorney General be permitted to redress the public interest, because it will otherwise go unredressed.

III. THE ATTORNEY GENERAL HAS NOT USURPED POWERS CONGRESS CONFIDED ELSEWHERE.

The suggestion is made by ICI that the purpose of this suit is to substitute the views of one subordinate executive agency for another—those of the "Department of Justice"

or the "Antitrust Division" for those of the Patent Office. ICI also says that "while the Justice Department has brought this suit in the name of the United States, it has done so without authority" (ICI Jan. 16 memo, p. 11). These allegations of mutiny within the Executive Branch are unfounded. Counsel for the government are authorized to state that this suit was brought by the Attorney General (who signed the complaint) on behalf of the United States, with full and exclusive authority to do so (28 U.S.C. §§ 516, 519).

In the same vein, ICI asserts that "Congress has given the Patent Office [rather than the Department of Justice] final authority to determine patentability on behalf of the United States" (ICI Jan. 16 memo, p. 11). This is fundamentally wrong. Congress has given *the federal courts* the final authority to determine patentability on behalf of the United States, and that is why the Attorney General brought this suit in this Court. In *Graham* v. *John Deere Co.*, 383 U.S. 1, 18 (1966), the Supreme Court emphasized the importance of the federal courts being responsible for final determination of patentability—pointing out the "notorious" discrepancy between the standards used in *ex parte* administrative determinations to grant patents, on the one hand, and in judicial, adversary proceedings, on the other hand. The purpose of this suit is *not* to substitute one executive agency's views for another's, but to place the decision where it belongs—in the courts.

Respectfully submitted.

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DATED: January 22, 1969

PLAINTIFF'S RULE 9(h) STATEMENT OF UNDISPUTED FACTS MATERIAL TO ITS MOTION FOR PARTIAL SUMMARY JUDGMENT AGAINST GLAXO DATED JUNE 13, 1969, FILED JUNE 27, 1969

1. Defendant Glaxo sells substantial quantities of bulk form griseofulvin, and oral antifungal antibiotic, in an unpatented form (regular particle size) to each of two United States companies, Johnson & Johnson, Inc. and Schering Corporation.

2. Defendant Glaxo sells substantial quantities of bulk form griseofulvin in a patented form (fine particle size) to each of two United States companies, Johnson & Johnson, Inc. and Schering Corporation.

3. Glaxo entered into agreements in 1959 with Johnson & Johnson, Inc. and Schering Corporation. These agreements expressly provide that such vendees are prohibited from reselling such purchased griseofulvin in bulk form. These agreements were maintained in effect at least until the filing of the complaint in this case.

4. Johnson & Johnson, Inc. and Schering Corporation adhered to these agreements not to sell such purchased griseofulvin in bulk form at least until the filing of the complaint in this case.

ORDER ON PLAINTIFF'S JUNE 13, 1969, MOTION FOR PARTIAL SUMMARY JUDGMENT AGAINST GLAXO (PROPOSED OCT. 23, 1969, BY PLAINTIFF, BUT NOT ENTERED)

The Court states the following undisputed facts and makes conclusions of law in connection with plaintiff's June 13, 1969, Motion for Partial Summary Judgment against defendant Glaxo Group Limited ("Glaxo") on the restraint on alienation issue, Glaxo's renewed defense of improper service of process, and Glaxo's June 20, 1969, Motion to Dismiss Plaintiff's June 13, 1969, Motion for Partial Summary Judgment.

I. SERVICE OF PROCESS ISSUE

A. Undisputed Facts

1. Glaxo is a British corporation which does not reside in the United States. Glaxo's 5/2/68 Answer to the Complaint, ¶ 5.

2. Glaxo and defendant Imperial Chemical Industries Limited ("ICI") entered into a patent pool licensing agreement dated April 26, 1960, licensing each other under their respective griseofulvin patents. GX-3, attached to the 10/31/68 Wallace affidavit.

3. Glaxo licensed Johnson & Johnson Inc. ("J&J") and Schering Corporation ("Schering") under Glaxo's and ICI's United States griseofulvin patents. GX-22, ¶ 2(a-b) and GX-23, ¶ 2(a-b) attached to the 6/13/69 Wallace affidavit.

4. The griseofulvin patent licenses from Glaxo to J&J and Schering are necessary for J&J and Schering to convert bulk form griseofulvin, which they purchase from Glaxo, to dosage form griseofulvin to avoid infringing the ICI pill patent. Glaxo's Answers to plaintiff's 7/16/68 Interrogatories Nos. 38, 39, 66, attached to the 10/17/69 Wallace affidavit.

5. J&J and Schering are required to pay Glaxo patent license royalties of 2½% on their sales of dosage form griseofulvin under the licenses of the pooled griseofulvin patents. Glaxo's Answer to plaintiff's Interrogatory No. 42, attached to the 10/17/69 Wallace affidavit; GX-22, ¶ 4 and GX-23, ¶ 4, attached to the 6/13/69 Wallace affidavit.

6. Glaxo collected a total of $210,000 in royalties from J&J and Schering in 1967. Glaxo's Answer to plaintiff 7/16/68 Interrogatory No. 42, attached to the 10/17/69 Wallace affidavit.

7. One half of the patent license royalties paid Glaxo by J&J and Schering are transferred by Glaxo to ICI pursuant to the patent pool license agreement. GX-3, ¶ 6, attached to the 10/31/68 Wallace affidavit; ICI's 9/16/68 Answer to plaintiff's 7/16/68 Interrogatory No. 42.

8. ICI sells to American Home Products Corporation ("AMHO") bulk form griseofulvin in so-called regular particle size. This form of griseofulvin is not, in bulk form, patented. ICI's 9/16/68 Answers to plaintiff's 7/16/68 Interrogatories Nos. 40 and 41; ICI's 11/8/68 Memorandum in Opposition to Plaintiff's Summary Judgment Motion, p. 6.

9. AMHO converts this regular particle size bulk form griseofulvin to so-called fine particle size griseofulvin, ICI's 4/29/68 Answer to Complaint ¶¶ 13, 18, 24; Glaxo's 5/2/68 Answer to Complaint, ¶ 10; ICI's 9/16/68 Answer to plaintiff's 7/16/68 Interrogatory No. 66, which is covered by the claims of Glaxo's United States Patent No. 3,330,727. GX-15, attached to the 6/13/69 Wallace affidavit; ICI's 9/16/68 Answer to plaintiff's 7/16/68 Interrogatory No. 66; 10/17/69 Wallace affidavit and GX-4 attached thereto.

10. AMHO is licensed to make such conversion of griseofulvin within the claims of Glaxo's fine particle size griseofulvin patent under the October 4, 1962, ICI-AMHO license agreement. GX-4, ¶ 10, attached to the 10/31/68 Wallace affidavit.

11. Pursuant to the ICI-AMHO agreement (¶ 11) AMHO pays royalties of 5% on its United States dosage form sales, see also ICI's 9/16/68 Answer to plaintiff's 7/16/68 Interrogatory No. 42, which are divided by Glaxo and ICI, pursuant to the Glaxo-ICI pool licensing agreement, GX-3, ¶¶ 5(a), 1(d), attached to the 10/31/68 Wallace affidavit.

12. ICI collaborated with Glaxo to exclude American Cyanamid from marketing fine particle size griseofulvin by advising Glaxo how to frame its fine particle size patent claims for such purpose. See GX-1 and GX-2 attached to plaintiff's 10/3/68 Memorandum (also attached as GX-1 and GX-2, to the 10/17/69 Wallace affidavit).

13. Glaxo's United States licensees J&J and Schering par-

ticipated in the procurement of Glaxo's fine particle size griseofulvin patent, and suggested means of enforcing it. See 12/5/68 Wallace affidavit in support of plaintiff's Motion to Amend the Complaint and attached exhibits.

14. Glaxo and ICI have refused to license other parties than J&J, Schering and AMHO under their United States griseofulvin patents. See 6/13/69 Wallace affidavit ¶ 2e and references cited therein.

15. Furthermore, Schering, J&J and Glaxo appear to have agreed that Glaxo is not to license additional parties in the United States. See 6/13/69 Wallace affidavit ¶ 2b and references cited therein.

B. Conclusions of Law

16. This is an antitrust case seeking an injunction against continued restrictive licensing practices by defendants and other appropriate relief.

17. The statute under which plaintiff served defendants ICI and Glaxo, 35 U.S.C. § 293, by its terms confers in personam jurisdiction on the District Court of the District of Columbia over alien patentees respecting civil actions relating to United States patents or rights thereunder, including licensing rights.

18. An antitrust case to enjoin restrictive patent licensing practices is a civil action within the meaning of 35 U.S.C. § 293 irrespective of whether the suit also seeks a cancellation of patents.

19. Substituted service of process on alien owners of United States patents does not violate due process of law. See *Japan Gas Lighter Ass'n.* v. *Ronson Corp.*, 257 F. Supp. 219 (D.N.J. 1966).

20. Application of 35 U.S.C. § 293 to effect service of process in a federal antitrust case does not violate Article 3 of the Constitution since this court has proper federal subject matter jurisdiction under this case. The fact that a long-arm statute can be used for nonfederal subject matter actions does not undermine its constitutionality when properly used in federal subject matter actions. See *United States* v. *First City National Bank*, 379 U.S. 378 (1965).

21. Glaxo's challenge to service of process in this case is denied.

II. THE ANTITRUST VIOLATION

A. Undisputed Facts

22. Glaxo sells patented fine particle size and unpatented regular size bulk form griseofulvin to J&J and Schering pursuant to patent license agreements. GX-22, ¶ 3, GX-23, ¶ 3, attached to the 6/13/69 Wallace affidavit; Glaxo's Answers to plaintiff's 7/16/68 Interrogatories Nos. 38 and 39, attached to the 10/17/69 Wallace affidavit.

23. In 1967 Glaxo sold J&J approximately $90,902 worth of regular size griseofulvin and $1,628,729 of fine particle size griseofulvin. In the same year Glaxo sold Schering approximately $227,135 of regular particle size bulk form griseofulvin and approximately $980,615 of bulk form fine particle size griseofulvin. Glaxo's Answers to plaintiff's Interrogatories Nos. 38 and 39, attached to the 10/17/69 Wallace affidavit.

24. Pursuant to the license agreements between Glaxo and J&J, and Glaxo and Schering, each such licensee "undertakes not to sell or permit its Affiliates to sell any griseofulvin in bulk to any Independent Third Party Without Glaxo's express consent in writing." GX-22, ¶ 3(c), GX-23, ¶ 3(c), attached to the 6/13/69 Wallace affidavit.

25. J&J and Schering have adhered to the bulk sales provision. See the 6/13/69 Wallace affidavit ¶ 4c and references cited therein.

B. Conclusions of Law

26. The provisions of Glaxo's patent license agreements with J&J and Schering restraining the resale of unpatented bulk form (regular size) griseofulvin are per se violations of Section 1 of the Sherman Act (15 U.S.C. § 1). See the June 4, 1969, Opinion of Judge Gasch in this case.

27. The provisions of Glaxo's patent license agreements with J&J and Schering restraining the resale of patented bulk form (fine particle size) griseofulvin are per se violations of Section 1 of the Sherman Act (15 U.S.C. § 1). *Adams* v. *Burke*, 84 U.S. (17 Wall.) 453, 456 (1873); *Hensley Equipment Co.* v. *Esco Corp.*, 383 F.2d 252, 263-64 (5th Cir. 1967); *Baldwin-Lima-Hamilton Corp. v. Tatnall Measuring Systems Co.*, 169 F. Supp. 1, 28-30 (E.D. Pa. 1958), *aff'd. per curiam*, 268 F.2d 395 (3d Cir.); *cert denied*, 361 U.S. 894 (1959); *United States* v. *Consolidated Car Heating Co.*, 1950 Trade Cases ¶ 62,656 (S.D.N.Y.).

28. Plaintiff's June 13, 1969, Motion for Partial Summary Judgment against Glaxo, that Glaxo's agreements with J&J and Schering restraining the resale of patented and unpatented griseofulvin are per se violations of Section 1 of the Sherman Act, is granted.

29. Glaxo's June 20, 1968, Motion to Dismiss plaintiff's June 13, 1969, Motion for failure to comply with local Rule 9 is denied because the record clearly shows plaintiff complied with such rule. See plaintiff's June 27, 1969, Memorandum.

PLAINTIFF'S RULE 9(h) STATEMENT OF UNDISPUTED FACTS MATERIAL TO ITS MOTION FOR PARTIAL SUMMARY JUDGMENT THAT THE GLAXO-ICI PATENT POOL LICENSE AGREEMENT CONSTITUTES A PER SE VIOLATION OF THE SHERMAN ACT, DATED DEC. 3, 1969

1. Defendants Glaxo and ICI agreed that ICI would not permit its licensee-purchasers to resell bulk form griseofulvin which they purchase from ICI.

2. Pursuant to its agreement with Glaxo, ICI entered into an agreement with its United States purchaser-licensee, AMHO, whereby AMHO agreed not to resell griseofulvin purchased from ICI in bulk form.

3. Pursuant to the ICI-AMHO agreement, ICI has sold substantial quantities of bulk form griseofulvin which, at least until the filing of the complaint in the case, AMHO has refused to sell to third parties in bulk form.

Respectfully submitted,

PLAINTIFF'S PREHEARING BRIEF CONCERNING PROPOSED FINAL JUDGMENT, DATED JULY 7, 1970

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, PLAINTIFF, v. GLAXO GROUP LIMITED AND IMPERIAL CHEMICAL INDUSTRIES LIMITED, DEFENDANTS.	Civil Action No. 558-68

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, PLAINTIFF, v. GLAXO GROUP LIMITED AND IMPERIAL CHEMICAL INDUSTRIES LIMITED, DEFENDANTS.	Civil Action No. 558-68

PLAINTIFF'S PREHEARING BRIEF CONCERNING PROPOSED FINAL JUDGMENT

Introduction

This Court has entered three orders holding that defendants engage in *per se* violations of the antitrust laws, by preventing bulk sale of the antibiotic drug griseofulvin. The government has proposed entry of a final judgment that would, among other things: (1) require defendants to offer to sell the drug in bulk on reasonable and nondiscriminatory terms and prices to all bona fide applicants (for so long as the defendants sell it in the United States to others, or for ten years, whichever is shorter); (2) require reasonable royalty-licensing of the patents that defendants used to support their illegal practices; and (3) restrain defendants from engaging in the future in similar restrictions upon the distribution of drugs. As the record in this case and the annexed affidavits[1] show, this relief is essential to the elimination of the present noncompetitive and anticompetitive state of the griseofulvin market, which has resulted from defendants' adjudicated antitrust violations.

In this brief, we will, first summarize the pertinent facts of record; and, second, show that the foregoing relief is necessary and within the scope of the Court's permissible

[1] Annexed to this Memorandum are affidavits from officers of Biocraft Laboratories, Zenith-Laboratories, and Dooner Laboratories (hereafter cited "*Biocraft Afft.*," "*Zenith Afft.*" and "*Dooner Afft.*," respectively). Also annexed is an affidavit from William B. Bohling (hereafter cited "*Bohling Afft.*"). Exhibits attached to such affidavits are identified thus: "*Biocraft Afft.*, Ex. A." "*Zenith Afft.*, etc.

discretion in fashioning an antitrust equity decree that will "effectively pry open to competition a market that has been closed by defendants' illegal restraints" (*International Salt Co. v. United States*, 332 U.S. 392, 401 (1947)), and that will insure that defendants are prevented from "entering into or acting under any similar agreement in the future" (*United States v. Trans-Missouri Freight Assn.*, 166 U.S. 290, 308 (1897)) by proceeding along "untravelled roads" to the forbidden goal (*International Salt, id.* at 400).

I. STATEMENT

Since griseofulvin was first marketed in the United States, the defendants have illegally prevented its sale in bulk form. Glaxo has sold the drug to its licensees, McNeil (a division of Johnson and Johnson, Inc.) and Schering, subject to illegal restraints against resale in bulk (Order of June 4, 1969, 302 F. Supp. 1). ICI has sold the drug to its licensee, Ayerst (also known as "AMHO"), subject to the same illegal restriction (Order of Nov. 20, 1969, 163 U.S.P.Q. 668), which ICI and Glaxo previously illegally agreed to impose (Order of April 30, 1970, 1970 CCH Trade Cases ¶ 73,189). And neither defendant will, itself, sell the drug to anyone but these three exclusive vendees,[2] with whom they previously agreed to the illegal restraint.

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[2] Defendant Glaxo does not have a written agreement with McNeil and Schering that they will be Glaxo's exclusive vendees. The government's motion to amend the complaint to charge a conspiracy among Glaxo, McNeil, and Schering, pursuant to which Glaxo agreed with McNeil and Schering not to deal with Merck and other third parties, was denied by the Court's Order of June 4, 1969 (302 F. Supp. at 15-16).

Documentary evidence showing the existence of such an agreement is part of the record in this proceeding. See Ex. 1, attached to Oct. 30, 1968, Wallace Affi., submitted with Govt. Reply Memo of Oct. 30, 1968; also designated GX-31, attached to J. Wallace Affi. of Aug. 19, 1969, submitted with Govt. Reply Memo of same date. The exhibit is a memorandum written by the Chairman of McNeil, narrating a conference among the chief officials of McNeil, narrating a conference among the chief officials of McNeil, Schering, and Glaxo, in which the member of Glaxo's Board of Directors who is responsible for advising the Board on such matters agreed to the demands of McNeil and Schering, that Glaxo would not deal with Merck or others, subject to final approval from the Glaxo Board. (An additional copy of the document is annexed hereto as App. A.)

The Glaxo Licenses

The April 1, 1959, license agreements between defendant Glaxo and McNeil (Johnson & Johnson), and Glaxo and Schering, are substantially the same. In them Glaxo granted a license under its patents and know-how "to make griseofulvin in the United States of America (subject always to any provisions in respect thereof hereinafter set forth) and to use and sell griseofulvin and to make, use and sell preparations containing the same" (¶ 2(b)).[3] The same paragraph also provided that the licensee shall be entitled "to have griseofulvin made for it in the United States of America for use and sale by it and Affiliates in accordance with this agreement." The agreement further provided that the licensee would attempt to purchase all its requirements of griseofulvin from Glaxo, "save for such griseofulvin as [the licensee] shall acquire from manufacture by or on behalf of [itself] or by any Independent Third Party authorised directly or indirectly by Glaxo so to do" (¶ 3(a)). Finally, the licensee undertook not to sell or to permit its Affiliates to sell in bulk any griseofulvin that the licensee acquired by manufacture by or on behalf of itself or by sale (¶ 3(c)). These are the agreements held to be per se in unreasonable restraint of trade, by this Court's Order of November 20, 1968.

The ICI-Ayerst Agreement

In 1958 ICI executed an agreement with Ayerst, designating Ayerst ICI's exclusive United States distributor (302 F. Supp. at 4). Pursuant to the provisions of a 1960 agreement with Glaxo (see Order of April 30, 1970),[4] in 1962 ICI executed a further agreement with Ayerst. The

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The uncontroverted fact is, as is shown hereinafter, that Glaxo does not deal with anyone in the United States but McNeil and Schering, and has turned down all requests from others. It is also uncontroverted that ICI has agreed not to sell griseofulvin to anyone in the United States but Ayerst.

[3] These agreements are GX-22 and GX-23, attached to Affts. of J. Wallace, dated June 13, 1969, filed with the Govt. Notice of Motion and Motion for Partial Summary Judgment against Glaxo, having the same date.

[4] The 1960 Glaxo-ICI agreement provided that ICI would not sell and would "use its best endeavors to prevent" licensees from selling in bulk. ICI acceded to this clause on the basis that Glaxo was to impose the same restriction upon its licensees (*Bohling Affts.*, GX-11e, ¶ 4(e)).

1962 agreement provided that ICI would sell griseofulvin to Ayerst, subject to a bulk sales restriction (302 F. Supp. at 5), and that ICI would grant Ayerst a nonexclusive license to make, use, and sell griseofulvin in dosage form, under ICI's and Glaxo's patents, from the bulk griseofulvin sold to Ayerst by ICI (¶ 11, GX-4 cited at 302 F. Supp. 5). As appears below, the significant aspect of the license to "make" was that Ayerst thus acquired the right to pulverize into microsize griseofulvin, pursuant to Glaxo's microsize patent,[5] the regular form griseofulvin that ICI sold it. The foregoing 1962 agreement is that held to be per se in unreasonable restraint of trade by this Court's Order of June 4, 1969.

Glaxo and ICI Refuse to Sell

The defendants Glaxo and ICI have consistently refused to sell the product in bulk to independent drug manufacturers, and they have thus prevented the sale of the drug by generic drug houses, private label sellers, or other independents. Thus Glaxo refused to sell to Zenith (*Zenith Afft.*, ¶ 7) and Dooner (*Dooner Afft.*, ¶ 7, Ex. 7, Ex. 9). ICI similarly declined to sell to Biocraft (*Biocraft Afft.*, ¶ 8), Zenith (*Zenith Afft.*, Ex. C), and Dooner (*Dooner Afft.*, ¶ 10, Ex. 19, Ex. 26). Nor does Glaxo sell to any other independent (see Glaxo Ans. to Int. No. 74).

Glaxo Refuses to License

Moreover, defendant Glaxo steadfastly refuses to license its patent on microsize griseofulvin (Glaxo Ans. to Int. No. 73-74), which is the only form of the drug for which there is a significant market (see, e.g., *Zenith Afft.*, ¶ 9; *Dooner Afft.*, ¶ 9). Without a license from Glaxo or ICI on the microsize griseofulvin patent—and neither defendant will grant one—the only possible noninfringing source of supply of bulk microsize griseofulvin is one of the defendants or one of their three licensees.[6] But none will sell.

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[5] The microsize patent (U.S. Pat. No. 3,330,727, issued Aug. 11, 1967) claims griseofulvin "having a specific surface area of at least 0.75×10^4 cm.2/g." As is shown below, such griseofulvin is the commercially significant type.

[6] Regular griseofulvin, if it could in some way be obtained in bulk, can be converted into microsize griseofulvin, but so doing would infringe Glaxo's

McNeil and Schering Refuse to Sell

Before and since the filing of this complaint the defendants' vendees have, pursuant to their unlawful agreements with defendants, refused to sell the product in bulk to generic drug houses or other independents. Thus, Glaxo's licensee McNeil turned down Dooner's request for griseofulvin, stating that it was a seller of dosage form drugs only and would not sell in bulk (*Dooner Afft.*, ¶ 8, Ex. 12). Similarly, Schering advised Dooner that it would not sell bulk griseofulvin (*ibid.*, Ex. 14).

The licensees knew that they both had identical licenses, since Glaxo made it clear to them that they stood on an identical footing. From start to finish of the negotiations Glaxo so advised them (see *Bohling Afft.*, GX-3 through GX-8) and the licensees met with each other and Glaxo to work out the license terms (see *Bohling Afft.*, GX-9; App. A).[7]

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microsize griseofulvin patent. We believe that this fact is uncontroverted. That ICI has so believed is shown by *Bohling Afft.*, GX-2. This document is a memorandum by Dr. Cusa, a top official of ICI, in which he states how he impressed upon Squibb the "impossibility of Squibb trading in griseofulvin without a license from Glaxo under the ICI and Glaxo patents." This occurred in the course of Cusa's explaining why Squibb was unable to secure griseofulvin from the defendants, who each turned Squibb's requests down (*Bohling Afft.*, GX-1b, GX-2).

[7] It is thus obvious that these licensees; knowledge that they were all subject to parallel restrictions against bulk sales has assured them that they were buying griseofulvin "packaged in a competition-free "wrapping" (*United States* v. *Parke Davis Co.*, 362 U.S. 29, 47 (1960)); and assured them that their fellow-licensees would not (as they did not) take advantage of the opportunity to increase revenue by selling the antibiotic in bulk and thereby indirectly capture a larger share of the total sales market. The defendants' licensees have, therefore, been the beneficiaries of the restraints on alienation, even though it was the licensees' freedom of action that was restrained by the unlawful agreement. In this regard, the economic effect of the bulk sales restriction has been to restrain *and* benefit the licensees in the same way that a vertical price fix restrains *and* benefits the merchants who join the combination put together by the seller who engages in resale price fixing. See *Atty. Gen. Nat'l Comm. Antitrust Rep.* 154 (1955).

That the bulk restriction on each licensee was the *quid pro quo* for the others is further shown by *Bohling Afft.*, GX-10, and GX-11. In GX-10d (¶ 4(e)), M. J. Methven of ICI's Legal Department gave his opinion of the then still unexecuted 1960 Glaxo-ICI agreement (subsequently held to be illegal in this Court's April 30, 1970, Order). In commenting on the bulk sale restriction to be imposed on Ayerst, Methven queried ICI's Pharmaceutical Division Secretary Bland, "Are you prepared to accept the obligation contained in this Clause?" Bland replied (GX-11e) that they *were* willing to accept the bulk

Ayerst Refuses to Sell

The only potential source of any form of bulk griseofulvin at any price is ICI's vendee Ayerst. Shortly before the filing of the complaint in this case, as a result of the government's investigation of the licenses involved, Ayerst and ICI agreed to eliminate the clause in their contract forbidding sales in bulk (see Order of June 4, 1969, 169 F. Supp. at 8; *Hoare Afft.*, ¶ 6).[8]

But this possible chink in the defendants' monopoly wall around the antibiotic is only illusory for two reasons: First Ayerst will sell bulk griseofulvin only in regular size form, a product of limited commercial value, not the commercially superior microsize form (see, e.g., *Zenith Afft.*, ¶ 7, ¶ 9; *Dooner Afft.*, ¶ 9). Such regular griseofulvin can be micronized (or pulverized into fine powder), but then the consequent product infringes Glaxo's microsize patent, which Glaxo refuses to license (p. 6 & note 6, *supra*). Second, Ayerst's offer to sell is illusory, because of the steep price, even if the purchaser elected to run the risk of an infringement suit by Glaxo.

Bulk "offer." After this suit was filed, Ayerst made offers to sell regular size griseofulvin in bulk. Ayerst quoted Zenith prices ranging from $123 per kilogram to $117 per kilogram (*Zenith Afft.*, Ex. A). Ayerst quoted Dooner a $118 price (*Dooner Afft.*, ¶ 9). To this base cost, before a total cost or price figure can be arrived at, there must be added the costs of micronizing, packaging, and distribution (see *Biocraft Afft.*, ¶¶ 4-5). The end figure—starting from the $117-$123 base quoted by Ayerst—is so high that a generic or private label house, which competes with the brand-name, highly-advertised products of defendants' licensee-distributors by selling "Brand X" at a 30%-40% lower price, cannot possibly market the drug (*Biocraft Afft.*, ¶¶ 10-11; *Dooner Afft.*, ¶ 9).

This is the well-known "squeeze play," condemned in the antitrust literature.[9] The price of the bulk drug is

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sales restriction to be imposed on Ayerst, because Glaxo "are imposing a similar obligation on all their licensees."

[8] The *Hoare Afft.* was made of prior record in thus case by ICI and is referred to in 169 F. Supp. at 5, 6, 7.

[9] See, e.g., *United States* v. *Bethlehem Steel Corp.*, 168 F. Supp. 576, 612-13 (S.D.N.Y 1958).

pegged so high, relative to the realizable price on the end product, that the margin is squeezed to zero or negligibly thin. As a result, the company so unfortunate as to be dependent on its competitor as a source of supply is itself squeezed out of existence.

Dosage "offer." ICI's distributor Ayerst has also offered to sell microsize griseofulvin, but in dosage form only—not in bulk. Again, this is an illusory offer, because of the economics of the business and the "squeeze." As the *Biocraft Afft.*, ¶¶ 4-5 shows, the generic or private label drug house must undersell the advertised product by a significant price margin (about a third less) to induce purchase of its "Brand X," even though the product (as it would be, here) is substantially the same, since the source of the basic ingredients is the same. Thus, whatever its reasons, Ayerst, the only firm that will offer to sell griseofulvin in any form to independent drug firms, is willing to sell dosage form griseofulvin only at such a high price that the margin is completely squeezed out. See *Biocraft Afft.*, ¶¶ 9-10; *Zenith Afft.*, ¶¶ 8-9.

Present State of Market

In the wake of this Court's rulings that defendants may not lawfully agree, as they did, with their distributor-licensees that bulk form griseofulvin would be kept out of the hands of generic drug houses, private label houses and other unduly competitive elements of the drug industry—the situation still remains one in which the bulk griseofulvin is kept out of the hands of such elements. The defendants sell only to their licensees, and will not license or sell microsize griseofulvin to anyone else; nor will defendants' licensees resell bulk microsize griseofulvin. To this day there is no noninfringing source of supply for bulk microsize griseofulvin available to generic houses or other independent drug companies in this country.[10] Between restrictive agreements, refusal to deal, refusal to license, and use of the "squeeze play"—the market is kept stable and no changes occur.

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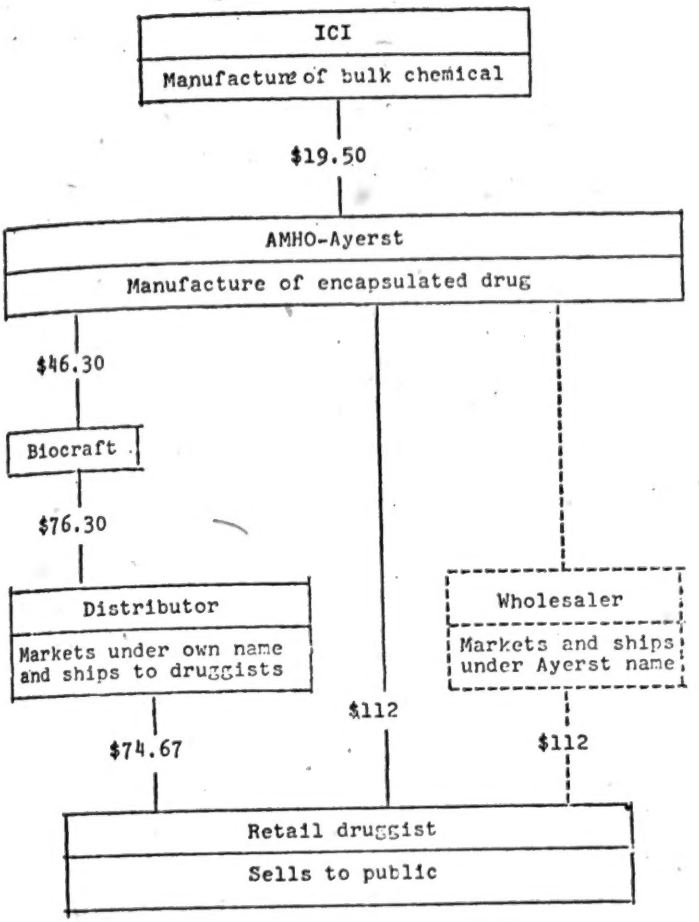
[10] There are five foreign licensees, Lovens of Denmark, Nyegaard of Norway, Hoechst of Germany, Clin-Comar of France, and Takeda of Japan. None is permitted to sell bulk griseofulvin to or for persons in the United States. Glaxo Ans. to Int. No. 64 (copy annexed hereto as App. B).



PRICE AND DISTRIBUTION STRUCTURE FOR GRISEOFULVIN AMHO OFFERS IN DOSAGE FORM AT $46.30 PER 1000, PER ICI BR., pp. 22-23

Note: All prices are on a basis of 250 mg., in 1000's.

Unless the independents are given the chance to procure microsize griseofulvin in bulk, on the same basis as the defendants' licensees, they will remain frozen out of the market. As the *Dooner Afft.*, ¶¶ 7-12, shows, despite his company's extraordinary efforts to procure the drug domestically or abroad it has been impossible for it to do so.

The effect is that the public is denied the benefit of the independents' and generic sellers' competition, in the form of price (see *Biocraft Afft.*, ¶¶ 4-5, ¶ 11; *Zenith Afft.*, ¶ 11; *Dooner Afft.*, ¶ 13, ¶ 16) and otherwise.

II. THE PROPOSED DECREE IS NECESSARY TO PRY OPEN THE MARKET CLOSED BY, AND PREVENT REVIVAL OF, THE ILLEGAL RESTRAINTS.

A. The General Principles Applicable to Antitrust Equity Relief

The Supreme Court has frequently declared the principles to be applied in determining relief in an equity suit brought (as here) by the United States, pursuant to Section 4 of the Sherman Act, to "prevent and restrain violations of" that Act.[11] In so doing, the Court has strongly emphasized the importance of adequate relief, since the type of relief granted will determine whether "the government has won a lawsuit and lost a cause." *International Salt Co. v. United States*, 332 U.S. 392, 401 (1947). Without relief that effectively and fully dissipates the competitive evils condemned in the antitrust adjudication, the net effect of the lawsuit is negligible—"the Government in its effort to free the . . . business of monopoly and unreasonable restraints would have won the battle but lost the war." (*International Boxing Club v. United States*, 358 U.S. 242, 259, (1959)).

The primary objectives of such a decree are to dissipate the past market effects of the restraint and to assure, so

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[11] 15 U.S.C. § 4. Doubtless, similar principles apply to equity suits brought by private patent-antitrust suitors (see *Mercoid Corp. v. Mid-Continent Co.*, 320 U.S. 661, 670 (1944)); but the principle that courts of equity "go much farther" to give relief in furtherance of the public interest is even more forcefully underscored in the context of a suit brought by the Attorney General to vindicate the public interest (*United States v. First Nat. Bank*, 379 U.S. 378, 383 (1965); *Porter v. Warner Co.*, 328 U.S. 395, 397-398 (1946); see *Virginian R.R. v. System Federation*, 300 U.S. 515, 552 (1937)).

far as may be practicable, that the wrongdoers shall not again violate the statute. The courts recognize that illegal restraints of trade may be achieved in many ways, and therefore the decree must be broad enough in scope, first, that it will "effectively pry open to competition a market that has been closed by defendants' illegal restraints" (*International Salt*, 332 U.S. at 401), and, second, that the alternative roads to accomplishing the forbidden end be closed off to the defendants (*ibid.*).

The Supreme Court has warned that it is "contrary to common experience" to assume that a violator of the antitrust laws "will relinquish the fruits of his violation more completely than the court requires him to do" (*id.* at 400); and, therefore, it has said, the defendant must be expected to employ "more subtle and informed" methods in the future, and ones which will be "more difficult to prove" than those methods condemned in the original litigation—i.e., than those methods that established the anticompetitive market structure found to be illegal (*ibid.*).

Hence, the defendants do not come before the court in the posture of asking for a decree that is to be written on a clean slate. Having been adjudicated as violators of the antitrust laws, the defendants must expect to have all doubts resolved against them (*Hartford Empire Co. v. United States*, 323 U.S. 386, 409 (1945); *Local 167 v. United States*, 291 U.S. 293, 299 (1934)) and to be "fenced in" by the court (see e.g., *Federal Trade Commission v. Mandel Bros.*, 359 U.S. 385, 392 (1959); *United States v. Crescent Amusement Co.*, 323 U.S. 173, 188 (1944)). Accordingly, in framing antitrust decrees, equity courts do not leave guilty defendants with all the freedoms that an innocent party would enjoy.[12]

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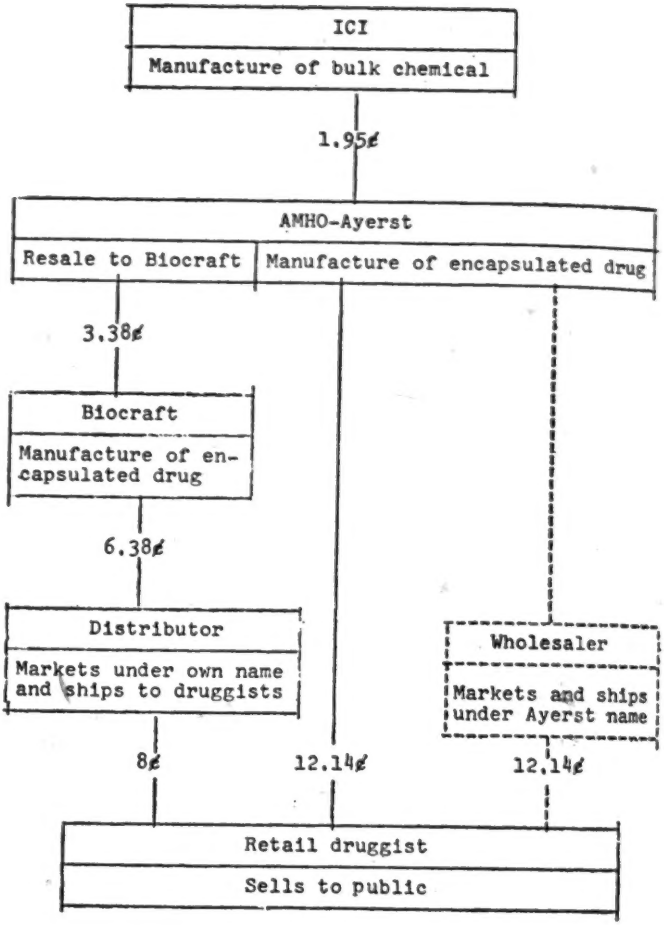
[12] The present defendants may argue that they should be given more lenient treatment, on the theory that they did not realize that their conduct was unlawful or else that *Schwinn* was a radical departure from the state of law existing at the time defendants began engaging in these restrictive practices. In the first place, the "ancient rule against restraints on alienation" long predated *Schwinn*. See, e.g., this Court's June 4, 1969, Order, 302 F. Supp. at 9, n. 36, and 10, n. 43 (citing restraint on alienation cases in the Supreme Court over the last century, as well as a 350-year old English authority). In the second place, even if defendants believed that their acts were within the shelter of rights given by the patent laws or other laws, if we assume that to be the fact, there would be no ground for entering a decree with merely narrow and restricted prohibitions that fail to accomplish all that the public interest requires.



PRICE AND DISTRIBUTION STRUCTURE FOR GRISEOFULVIN AMHO OFFERS IN BULK AT $135 PER KILO IN 250-KILO LOTS

Note: All prices are on a 250 mg. basis, per capsule, in cents. For a 100's basis, convert to dollars by multiplying cents by 100.

B. A Decree Requiring Bulk Sales of Griseofulvin On Nondiscriminatory Terms is Essential to Prying Open the Market.

1. There is a manifest need for bulk sales relief. As long as griseofulvin has been marketed in the United States, the defendants have illegally prevented its sale in bulk form. Glaxo and ICI have sold the drug in bulk to their licensees, McNeil, Schering, and Ayerst (AMHO), expressly subject to illegal restraints against resale in bulk, which they agreed with one another to impose. The defendants have consistently refused to make bulk form microsize griseofulvin available to generic drug houses and other independents. And similar arrangements with foreign licensees have eliminated foreign sources of supply. At the same time, defendants' three exclusive distributors in the United States have also declined to sell the drug. They bought the griseofulvin franchise from the defendants "packaged in a competition-free wrapping" (*supra*, p. 7 and n. 7), and they have displayed no inclination to peel off that wrapping—even after the government's investigations and the institution of this suit prompted defendants to state that they would relinquish their express contractual prohibitions against resale of bulk griseofulvin. Thus the licensees are quite aware that they have been joint beneficiaries of defendants' restrictive scheme, even though it was the licensees' freedom of action that the scheme restrained.

One must therefore anticipate that the defendants' licensees will continue, as they have to date, to refuse to sell in bulk—irrespective of this Court's ruling that the express contractual prohibition against reselling in bulk was a *per se* violation of the Sherman Act.

In short, to this day, notwithstanding Glaxo and ICI's abeyance of the illegal restriction, there is no noninfringing source of supply for bulk microsize griseofulvin available to

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Indeed such arguments wholly misconceive the basis upon which antitrust relief is predicated. The defendants are not to be penalized because of any mistaken beliefs in the scope of their patent privileges, nor, on the other hand, are such beliefs grounds for giving them favored treatment. The sole consideration is that the prohibitions to which defendants are subjected should be directed toward securing full compliance with the law which they violated and to prying open to competition the market that has been closed by their illegal restraints (*International Salt*, 332 U.S. at 401).

generic houses or other independent drug companies in this country. Consequently, without an order of this Court, requiring the defendants to deal with independent drug companies on a fair and nondiscriminatory basis, the latter will continue to be kept out of the market. The public will be denied the benefits of their competition, in the form of price and otherwise. And the impact of this litigation on the griseofulvin market, instead of prying it open to competition, will have been negligible. For these reasons, the government urges the Court to require the defendants, so long as they sell the drug to anyone in the United States, to sell to independent drug companies on the same basis.[13]

2. *Besser case.* The authorities amply support the court's power to enter such relief. Thus, in *Besser Mfg. Co. v. United States,* 343 U.S. 444 (1952), the defendants appealed from the provisions in an antitrust judgment requiring them to grant their patent licensees the option of purchasing the patented machinery. The Court upheld the decree, summarily declaring: "The compulsory sale provision of the judgment, strenuously attacked, is likewise [like compulsory patent licensing] a recognized remedy" (*id.* at 447).

International Salt case. Earlier, In *International Salt Co. v. United States,* 332 U.S. 392 (1947), the Supreme Court upheld a decree permanently requiring the defendant "to offer to lease or sell or license" its present type of patented machinery and other types which might be developed "to any applicant on nondiscriminatory terms and conditions" (*id.* at 398-399 and n. 7). In that case, the Court first affirmed the grant of summary judgment against the defendant's patent licensing practices. Defendant International had licensed its patents on machinery for utilization of salt products so that other suppliers were foreclosed from selling salt to the licensees (who were bound to give defendant the right of first refusal on their orders). The Court ruled that "it is unreasonable, *per se,*

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[13] A limit of ten years on such order is proposed, because it is believed that such period of time should be sufficient for market conditions to become reestablished to the basis that would have obtained, had the antitrust violations not occurred. The further limitation on the proposed order, imposing the obligation only so long as defendants sell to others, reflects an attempt to avoid requiring defendants to engage in the sale of a product in which they no longer wish to deal (should such become the case).

to foreclose competitors from any substantial market" (*id.* at 396).[14]

International also "strongly objected" to the provision of the decree requiring it to offer to sell its patented machinery to any applicant on nondiscriminatory terms and conditions (*id.* at 398-400). International contended that, since it had never threatened to violate any decree entered in the case, it would be sufficient merely to enjoin its future use of the *per se* illegal agreements. It maintained that it was "entitled to stand before the court in the same position as one who has never violated the law at all—that the injunction should go no further than the violation or threat of violation (*id.* at 400).

The Supreme Court disagreed. It said that it would be "contrary to common experience" to assume that the defendant, having violated the antitrust laws, would "relinquish the fruits of his violation more completely than the Court requires him to do" (*ibid.*). The Court said that in the future the defendant might be expected to use "more subtle and informed, and more difficult to prove" methods than those he had used to restrain trade in the first place and which the Court had condemned (*ibid.*). Therefore, the Court required compulsory sales of the machinery on nondiscriminatory terms to remove any temptation for the defendant to revive the restrictive practice by subtler techniques—what the dissenting Justices called "a precautionary screw to hold the appellant down from disobeying the court's decree" (*id.* at 404).

United Shoe case. Again, in *United States v. United Shoe Machinery Corp.*, 110 F. Supp. 295 (D. Mass. 1953), aff'd, 347 U.S. 521 (1954), the court required the defendant to offer to sell any type of machinery that it had offered to lease. The defendant argued that such a decree would discriminate against it, because it would be under a limitation to which its competitors would not be subject (110 F. Supp. at 350). The court ruled, however, that compulsory sales relief was necessary to root out the defendant's monopolistic practices, and that defendant had placed itself "in a different class than other people" by engaging in

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[14] Although the facts in *International Salt* and *Glaxo* cases are not identical, it is to be noted that in the instant patent case, also, the patentee has engaged in *per se* illegal practices designed to, and which did, foreclose generic drug houses and other independent drug manufacturers from a substantial market.

such practices (*ibid.*). Accordingly, the court required the defendant to offer to sell its machinery, so long as defendant continued to offer to lease such machinery, on such terms as would not "make it substantially more advantageous" for its customers to lease its machinery rather than to buy a machine (*id.* at 351, 352).

It is thus seen that judgments requiring the defendant to sell the patented product on a reasonable and nondiscriminatory basis have been entered and subsequently approved by the Supreme Court in a number of patent antitrust cases.[15] We have also shown, we submit, that such relief is necessary in the present case, to permit entry into the griseofulvin market by generic drug houses and other independent drug manufacturers who have been foreclosed from that market because of defendant's illegal restrictive practices.

C. Reasonable Royalty Licensing of Griseofulvin Patents Is Essential to Prying Open the Market.

Reasonable royalty licensing of the griseofulvin patent, particularly the Glaxo microsize patent, is necessary, in addition to compulsory sales relief, to assure third parties alternative sources of supply should defendant elect no longer to sell in the United States. Both defendants

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[15] Compulsory dealing provisions were also contained in the judgment in *International Boxing Club* v. *United States*, 358 U.S. 242, 61 (1959). That decree required the defendants to lease their respective sporting arenas upon request by qualified promoters, upon reasonable rentals and security.

Many consent decrees have provided for compulsory sale on reasonable terms and conditions. E.g., *United States* v. *Automatic Sprinkler Company of America*, CCH Trade Cases, ¶ 62,230 (E.D. Ill. 1948) (automatic fire sprinklers); *United States* v. *International Nickel Company of Canada, id.*, ¶ 62,280 (S.D.N.Y. 1948) (rolling mill metal); *United States* v. *Standard Register Company, id.*, ¶ 62,533 (D.D.C. 1949) (office machine parts); *United States* v. *Liquid Carbonic Corporation, id.*, ¶ 67,248 (E.D.N.Y. 1952) (carbon dioxide); *United States* v. *Republic Steel Corporation, id.*, ¶ 67,510 (N.D. Ohio 1953) (corrugated culvert sheets); *United States* v. *Western Newspaper Union, id.*, ¶ 67,557 (S.D.N.Y. 1953) (printing supplies and paper); *United States* v. *Eastman Kodak Company, id.*, ¶ 67,920 (W.D.N.Y. 1954) (color film processing materials); *United States* v. *Ernest Lowenstein, Inc., id.*, ¶ 68,106 (S.D.N.Y. 1955) (imitation stones); *United States* v. *Reddi-Wip, Inc., id.*, ¶ 68,187 (S.D. Cal. 1955) (dispensing heads); *United States* v. *Dover Corporation, id.*, § 68,623 (D.C. Tenn. 1957) (elevator pumps); *United States* v. *Torrington Company, id.*, ¶ 68,611 (D.C. Conn. 1957) (sewing machine needles); *United States* v. *Jas. H. Matthews & Company, id.*, ¶ 69,187 (W.D. Pa. 1958) (cemetery markers); *United States* v. *General Dynamics Corporation, id.*, ¶ 70,401 (E.D.N.Y. 1962) (carbon dioxide).

oppose the portion of the Government's proposed Final Judgment (¶¶ IV(D) and IV(F)) that would require each defendant to grant to each applicant therefore a nonexclusive, unrestricted license, on reasonable and nondiscriminatory terms and royalty rates, on griseofulvin patents and technical data.

1. We may assume that ICI's objection to a decree respecting granting licenses under its patent is primarily a matter of principle, for ICI has already assured the Court that it would and has granted nonexclusive licenses under the ICI patent, on reasonable terms and conditions (see 302 F. Supp. at 5-6). Glaxo, however, continues to refuse to grant any additional licenses under its microsize patent. Moreover, although ICI has granted Ayerst a sublicense under Glaxo's microsize patent, ICI is unwilling to license any additional such applicants, and it appears to take the position that the agreement between it and Glaxo (held illegal in the Order of Nov. 20, 1969) precludes any such additional grant.

Glaxo. Glaxo's patent is an absolute barricade to entry into the griseofulvin market. The only way to sell microsize griseofulvin in the United States, without being an infringer of Glaxo's microsize patent, is to buy the product from Glaxo or a licensed source.[16] As has been demonstrated, however, Glaxo will not sell griseofulvin to generic drug houses or other independent drug manufacturers, nor will its licensees.

If Glaxo were placed under the compulsory bulk sale order we have proposed, and discussed in Part B, *supra*, then it might be that no such microsize license from it would be necessary. But the order we have proposed goes only so far: it would impose on Glaxo the obligation to sell only so long as Glaxo continued to sell to others (i.e., its licensees Schering and McNeil), and if Glaxo stopped selling in bulk to them it would no longer be under such obligation. Thus, unless our limited compulsory sales proposal was broadened—and we are reluctant to request such broadening, if it can be avoided by adoption of reasonable alternatives—Glaxo could elect to stop selling to its present licensees (or they could, under the license agreements, elect to manufacture for themselves), with the

[16] Microsize griseofulvin is the commercially significant form (p. 6, *supra*).

result that neither Glaxo nor any other noninfringing source of bulk microsize griseofulvin would be available to generic drug sellers and other new entrants into the market. A license under Glaxo's microsize patent is thus seen to be needed to preserve access to the market for any newcomer attracted by the decree in this case.

ICI. Defendant ICI sells bulk regular size griseofulvin but does not sell bulk microsize griseofulvin.[18] Since ICI does not sell bulk microsize griseofulvin, no order has been proposed that would require it to do so. Nevertheless, as a necessary complement to any decree requiring ICI to sell griseofulvin in bulk to any applicant on the same terms it now offers others (such as Ayerst), there should be a provision conferring on the vendee a license to grind up the bulk product into microsize griseofulvin, so that the goods purchased from ICI could be utilized and resold on the commercial market.

Finally, moreover, the option of a right to make, use, and sell griseofulvin at a reasonable royalty rate should be kept open as a reasonable alternative for those applicants who wish to make the product, or procure it from some source other than the defendants. This will not only preserve the freedom of action of potential entrants into the market, but act as a damper upon unreasonable price demands by the defendants (compare Ayerst's illusory offers, pp. 7-10, *supra.*)

2. In cases such as the present one, in which defendants' violation of the Sherman Act has been grounded on their use of the monopoly power conferred by their patents, the courts have customarily decreed reasonable royalty licensing, in order to pry the market open to newcomers.[19] See, e.g., *Besser Mfg. Co. v. United States* 343 U.S. 444, 449 (1952); *United States v. United States Gypsum Co.*, 340 U.S. 76, 94 (1950); *United States v. National Lead Co.*, 332 U.S. 319 (1947); *Hartford Empire Co. v. United States*, 323 U.S. 386, 417 (1945); clarified, 324 U.S. 570, 573-574

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[18] It sells regular size griseofulvin to Ayerst, who then micronizes the product into microsize griseofulvin, pursuant to a sublicense granted it by ICI.

[19] Or, as Counsel for defendant ICI has put it—"There admittedly is ample precedent for the grant of such relief [compulsory patent licensing] after antitrust violation has been proved." Memorandum of Points and Authorities in Support of Motion by Defendant Imperial for Partial Judgment Under Rule 12(c) or Rule 56, p. 2, served Oct. 15, 1968.

(1945). Indeed, so conservative a source as the 1955 *Report of the Attorney General's National Committee to Study the Antitrust Laws* has declared that "it is settled that where necessary to restore effective competition, compulsory licensing at reasonable rates can be decreed" (*id.* at 255).

The need and appropriateness of compulsory licensing relief is amply demonstrated by the record, as shown above. We now turn to some special provision of this portion of the proposed decree.

3. *Mechanics of Licensing.* The decree proposed here is similar to that upheld in *National Lead, supra,* which required reasonable-royalty licensing of presently-owned titanium pigment patents and those issued to defendants for the next five years (332 U.S. at 328, n. 4, ¶ 4(d), ¶ 7). Such subsequently-acquired patents were also covered by the *Hartford Empire* (323 U.S. at 417-418) and *Gypsum* (340 U.S. at 94) decrees. This relief is necessary to insure that new entrants into the field will not be first drawn in and then left stranded by the dynamics of the industry—which in recent years has seen microsize griseofulvin almost totally wipe regular size griseofulvin out of the market place.

The method for determining reasonable royalty is also based on the *Gypsum* decree (340 U.S. at 94, 101-103).

4. *Technical information.* The proposed decree covers technical information ("technical data") as well as patents. The reach of the Sherman Act to secure reasonable-royalty, nondiscriminatory licensing of unpatented technical information in appropriate circumstances seems as indisputable as compulsory patent licensing. In *National Lead,* 332 U.S. at 355, the Supreme Court, in sustaining the district court's decree providing for such relief, declared:

> The need for technical information to accompany patent licenses in this field, at least where desired by a newcomer, is testified to repeatedly. If there be such need, the reasonableness of this limited availability of it as stated in the decree is hard to deny.

In the present case, the original pooling agreement between Glaxo and ICI (held to be in unlawful restraint of trade in the Apr. 30, 1970, Order) covered technical information. The agreement recites that Glaxo "is the owner

of valuable technical and other confidential information relating to griseofulvin not disclosed in the Glaxo patents" (¶ (B)) and the ICI desires "to receive and be authorised to use the know-how to make, use and sell griseofulvin and preparations containing the same" (¶ (C)). Glaxo undertook to transmit the know-how to ICI for its and its subsidiaries' use (¶ 2(a)) and ICI undertook to protect its confidentiality (¶ 8(a)) and to grant back to Glaxo know-how it obtained during the term of the agreement (¶ 10(b)). The subsequent license agreements (held illegal in the Order of Nov. 20, 1969) also contained "know-how" grants (¶¶ 4(i), 4(ii)). Moreover, Glaxo considered its know-how of sufficient value that it required the licensees to bind all their agents, employees, and independent contractors having access to it to keep it confidential; to agree to cease using it on termination of the agreement; and return to Glaxo all documents relating to it (¶ 7(a)).

Finally, defendant Glaxo has maintained in license negotiations, that the technical information aspects of the griseofulvin agreement were commercially important. Thus, in a meeting among top officials of Glaxo and McNeil (Johnson & Johnson) to plan the possible exploration of griseofulvin in the American market, Glaxo assured the head of McNeil that Glaxo not only had a patent position, but it had a considerable background of know-how, as well, which it believed would be important to McNeil (*Bohling Affi.*, GX-12).

In the circumstances, since the technical information relating to griseofulvin has been and presumably still is important to the parties, it should be made available to would-be entrants to the market and included in the decree along with patent licensing provisions.

D. The Decree Should Probit All Methods of Restraining Bulk Sales of Drugs

We do not understand defendants to oppose an injunction forbidding them from engaging in any further bulk sales restraints on the alienation of drugs.[20] (See e.g., Transcript of Proceedings, Jan. 23, 1969, pp. 99, 101-103.) It appears, instead, that objection is in some way made to a pro-

[20] ¶ 4(A) of the proposed Final Judgment prohibits restraints on the alienation of drugs.

hibition of other forms of restraints against the sale of drugs in bulk, contained in patent licenses.[21] As we understand defendants' position, they maintain that the decree should leave defendants free to restrain sales in bulk (1) by a licensee who itself manufactures griseofulvin or has a third party manufacture the drug for it, and even (2) by a licensee who buys regular size griseofulvin (as Ayerst does) and then makes microsize griseofulvin from it by grinding it into fine particles, pursuant to the license under the microsize patent. In short, the defendants wish this Court to allow them to follow other, somewhat less travelled paths by which they could effect a restriction against sales in bulk. We submit that the Court should not do so.

1. The practical economic shortcomings of so limited an injunction are illustrated by the background of Glaxo's negotiations with its licensees. As indicated previously (see note 2, *supra*), Glaxo met with McNeil and Schering in late 1958, to discuss possible third party suppliers of griseofulvin for McNeil and Schering. Mr. Brown, the President of Schering, "objected strenuously to Merck" on the ground that Merck would "press Glaxo continuously to permit general bulk sales" (App. A, p. 1, ¶ 5). The three firms decided that Merck should not be authorized as a bulk source, but that Penick (apparently less aggressive on this score) might be appropriate. They then entered into the license agreements involved in this case (see p. 4, *supra*), pursuant to which Glaxo licensed McNeil and Schering under the various Glaxo and ICI patents to make, have made, use and sell griseofulvin—subject to a restriction against bulk sales.

Under Glaxo's proposed decree in this case, Glaxo could in the future have McNeil and Schering buy their griseofulvin in bulk form from a supplier such as Penick, as the licensees involved in this case expressly contemplate (see p. 4, *supra*), and Glaxo would then be free to prohibit McNeil and Schering from reselling such griseofulvin in bulk to independent third party drug manufacturers.[22] This

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[21] ¶ 4(G) of the proposed Final Judgment prohibits agreements with United States patent licensees that prevent, restrain, or limit any party to the license agreement from selling any drug in bulk form. The paragraph also prohibits license restrictions against selling to generic drug houses or the like.

[22] The same restriction would apply to griseofulvin which McNeil or Schering made for itself.

Court should not sanction so transparent and facile a subterfuge to evade the impact of its decree.

Further shortcomings of an injunction limited to classic restraints on alienation are illustrated by the present ICI-Ayerst license (held to be in *per se* illegal restraint of trade in the June 4, 1969, Order). ICI sells Ayerst regular griseofulvin in bulk form. Ayerst then micronizes (grinds up into fine particles) this bulk form griseofulvin, pursuant to sublicense from ICI under the Glaxo microsize patent. Without such a sublicense Ayerst would infringe the Glaxo patent by "making" microsize griseofulvin. ICI also licenses Ayerst to make this bulk form griseofulvin (whether regular or microsize) into pills or capsules. Again, if such conduct were unlicensed, it would infringe ICI's dosage form patent.[23]

Under the defendants' proposal for a narrow decree, ICI could not lawfully prevent Ayerst from reselling the bulk regular size griseofulvin, immediately after Ayerst bought it from ICI; that would be a classic restraint on alienation. As soon as Ayerst pulverized this griseofulvin, however, on defendants' theory it would become completely proper and legitimate to prevent Ayerst from reselling this bulk griseofulvin, because the restraint upon its sale would now be a "manufacturing restraint" based upon the sublicense to make microsize griseofulvin under the Glaxo patent. By the same token, if Glaxo stopped shipping its griseofulvin to McNeil and Schering in microsize form (as it now does), and began shipping it in regular form (as ICI now does), then Glaxo could permissibly restrain the resale of the bulk griseofulvin after, although not before, the licensees pulverized it.

The defendants should not be free to continue to keep griseofulvin or similarly restrained drugs out of the hands of generic drug houses and independent manufacturers, whether by means of an alternative foreclosure device or another variation on the same one. The defendants will not willingly relinquish their restrictive and monopolistic program. They will continue its operation unless this Court closes off against them alternative paths to the same end which they reached by the contracts that the Court has already condemned under the antitrust laws. The Court

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[23] These two patents are those which the United States unsuccessfully sought to have declared invalid, earlier in this proceeding.

should therefore, we urge, dissipate the consequences of defendants' past wrongdoing and prevent revival of their restrictive program under a new device. The decree should accordingly prevent defendants from imposing any further restrictions on bulk sales of drugs, whether by means of the "sales license" restriction (restraint on alienation) they hitherto primarily relied upon to accomplish their illicit goals, or by means of the "make and have made license" restriction ("manufacturing restraint"), which is contained in the same agreement which has already been held unlawful and which has the same purpose and effect.

2. The Supreme Court has consistently held that an antitrust decree is not to be restricted to a mere prohibition of the precise conduct found to be illegal. On the contrary, the rule is that "the untravelled roads" to the forbidden goal of restraining competition should be closed as well as "the worn one" (*International Salt, supra,* 332 U.S. at 400). Thus the Court has said (*Gypsum, supra,* 340 U.S. at 88-89) that after an adjudication of antitrust violation a trial court—

> has the duty to compel action by the conspirators that will, so far as practicable, cure the ill effects of the illegal conduct, and assure the public freedom from its continuance. *Such action is not limited to prohibition of the proven means by which the evil was accomplished, but may range broadly through practices connected with acts actually found to be illegal.* Acts entirely proper when viewed alone may be prohibited. The conspirators should, so far as practicable, be denied future benefits from their forbidden conduct. [Emphasis supplied.]

In prescribing relief that, "to be effective, must go beyond the narrow limits of the proven violation" (*id.* at 90), the *Gypsum* Court therefore modified the decree before it, first, to increase its *geographic scope,* from the eastern territory (where the violation occurred) to the entire United States (*id.* at 90); second, to increase its *product scope,* from patented gypsum board (which the patents involved covered) to all unpatented gypsum products as well (*id.* at 90-91); and third, to increase its *conduct scope,* to forbid, broadly, "standardization of trade practices through concerted agreement" (*id.* at 91). In the remain-

der of this portion of this brief, we shall focus upon antitrust decree *conduct scope* decisions of the Supreme Court.

Similar agreements rule. The principle stated in *International Salt* and *Gypsum* has long been recognized in antitrust law. Given the ingenuity and inventiveness of business enterprise, the courts early recognized that merely to prohibit the precise scheme used by the defendants to effectuate an illegal restraint of trade would be inadequate to suppress the unlawful practices and prevent their revival in another form.[24] Accordingly, as early as 1897, within the first decade of the Sherman Act's existence, the Court said, "The injunction should go further, and enjoin defendants from entering into or acting under any similar agreement in the future" (*United States v. Trans-Missouri Freight Assn.*, 166 U.S. 290, 308 (1897)).

Acting on the "similar agreements" principle in *United States v. Crescent Amusement Co.*, 323 U.S. 173, 187-188 (1944), the Supreme Court upheld, over defendants' objections, an injunction which prohibited them (1) from entering into film-licensing franchise agreements with the purpose and effect of maintaining their theatre monopolies and preventing independent theatres from competing with them, and (2) from entering into "any similar combinations and conspiracies having similar purposes and objects.

In the instant Final Judgment we propose a prohibition of similar combinations and agreements having similar purposes and objects, in far more specific language than that expressly approved by the Supreme Court in the *Crescent* case. The complaint of excessive vagueness and generality—rejected in any event by the Court in its *Crescent* opinion (*ibid.*), therefore cannot be made here. The only other objection to ¶ IV (G) which we believe to be made by defendants is that it prohibits what defendants may assert are "lawful acts." We do not agree that the bulk sales restriction, which forecloses generic drug sellers

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[24] Congress' concern over the protean ingenuity of antitrust violators has been expressed legislatively and has led the Supreme Court in *International Salt* (332 U.S. at 400, n. 10) to declare that Congress intended that the decree in a Sherman Act case should go beyond "a simple prohibition of the particular practice proved before the court." Instead, the Court said, "Congress has intended decrees to deal with the future economic condition of the enterprise as well as past violations" (*ibid.*). The Court then went on to fence the defendant in so that he could not experiment with new means of foreclosing the market from competitors.

from the market and deprives the public of the benefits of their price-cutting and other forms of competition, is a legitimate commercial restraint or "lawful act" (see, e.g., *Klor's, Inc. v. Broadway-Hale Stores, Inc.*, 359 U.S. 207, 212-213 (1950)). But, as we shall now show, the Court need not reach that question, because the law is well-settled that, in prohibiting similar agreements, combinations, and conspiracies, the reach of the decree should extend to otherwise lawful acts.[25]

Prohibition of lawful acts rule. As the Court stated in *Gypsum* (*supra*, p. 27), acts entirely lawful and proper, when they are viewed alone, may be prohibited in the wake of an antitrust adjudication—in order to build a fence against defendant's changing the form of his conduct and then perpetuating the anticompetitive market structure built up by the original illegal conduct. Thus we may assume, *arguendo*, that it would be entirely proper and lawful for defendant Glaxo, were it writing on a clean slate, to foreclose generic drug manufacturers from the market by agreeing (as it has) with the Glaxo licensees (Schering and McNeil) that the latter would make microsize griseofulvin or have it made for them, that the two would be licensed to sell the patented product in dosage form, and that they could not sell it in bulk form. But even if we were to indulge in the assumption of the legitimacy of this type of bulk sale restriction, the paramount fact is that defendants do *not* now write these license agreements on a clean slate. They wrote them, first, as part of the same clause that contained an illegal restraint on alienation of bulk

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[25] We do not concede the legitimacy of any bulk sales restrictions on drugs, under the ancillary restraint theory (302 F. Supp. at 10) or any other theory, particularly when they occur (as here) in the context of a combination among two suppliers and three customers. To paraphrase *Klor's*, *supra*, they take from the generic drug houses their freedom to buy drugs in an open competitive market and drive them out of business as dealers in the defendants' products (see also, to the same effect as *Klor's*, *United States v. United States Gypsum Co.*, 333 U.S. 364, 398, 400 (1948) ("*Gypsum I*")). Moreover, they have been shown here to foreclose generic drug houses from a substantial market, contrary to the mandate of *International Salt*, 332 U.S. at 396; and *United States v. General Motors Corp.*, 384 U.S. 127, 145 (1966) (elimination of discounters by collaboration between dealers and supplier *per se* illegal). For the reasons set forth in the remainder of this brief, we believe that the Court has ample power to enter the proposed decree without even considering the question of whether bulk sales restraints that are not restraints on alienation are legitimate.

drugs. Second, the practice will perpetuate, in another guise, the same restrictions against competition by independent drug manufacturers caused by defendants' past illicit restraints on alienation. Consequently, even if what defendant Glaxo now seeks to have sanctioned by the Court were a lawful act, in itself, rather than an illicit one—the conduct should nonetheless be prohibited, to neutralize the continuing operating force of the defendants' past transgressions and thus prevent them from deriving "future benefits from their forbidden conduct" (*ibid.*).

Loew's case. The prophylactic rule that all restrictive practices (whether legal or illegal in themselves) associated with an unlawfully restrictive arrangement should also be prohibited was recently reaffirmed by the Supreme Court in *United States v. Loew's, Inc.*, 371 U.S. 38 (1962). The trial court had refused to enter various types of relief which the government sought as necessary to prevent the defendants from continuing their restrictive copyright licensing practices by more subtle, even if lawful, means. The Supreme Court reversed and remanded, holding (*id.* at 53):

> Some of the practices which the Government seeks to have enjoined with its requested modifications are acts which may be entirely proper when viewed alone. To ensure, however, that relief is effectual, otherwise permissible practices connected with the acts found to be illegal must sometimes be enjoined.

Accordingly, the Court granted a limited prohibition against "temporary" refusals to deal, reversing the lower court's denial of such relief. The defendants maintained that this conduct was no more than a legitimate exercise of their business rights, which are protected by the "*Colgate* doctrine," but the Court declared (*id.* at 55):

> No doubt temporary refusal to sell in broken lots to one customer while negotiating to sell the entire block to another is a proper business practice, viewed *in vacuo*, but we think that if permitted here it may tend to force some stations into buying pre-set packages to forestall a competitor's getting the entire group. In recognition of this the Government seeks a blanket prohibition against all temporary refusals to deal.

Consequently, the Court stripped defendants of their "*Colgate*" rights to "protect the interest of the Government in guarding against violations" (*id.* at 56).

Ethyl case. The same rule is further illustrated by the Supreme Court's decision in another patent licensing case, *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436 (1940). That case involved the licensing program on tetraethyl lead, a high-test gasoline additive. The issue was whether Ethyl could prevent the sale of gasoline containing tetraethyl lead, to unlicensed jobbers and refiners. The licensing system was, in many respects, similar to that involved in this case, because the subtle effect of the restraint against sale to unlicensed jobbers and refiners was to keep the product out of the hands of those (like the generic sellers in the instant case) who were price cutters or whose competitive activities would otherwise jeopardize the "orderly marketing" strategy of the patentee.

There was no contract or agreement which purported to prescribe retail prices or to exact any price policy from the jobbers (*id.* at 450). But it appeared that Ethyl had acquired the power to exclude unlicensed jobbers from the market (as defendants have the power to exclude generic manufacturers), by virtue of the monopoly power, in itself lawful, conferred by the patent (*id.* at 452). The Supreme Court therefore found that the potentiality in the licensing system for stabilization of the market was sufficient to bring it within the prohibitions of the Sherman Act.

Ethyl's patent licensing system, viewed apart from the subtle price stabilization context in which it was set, apparently was lawful, at least in part.[26] But, since the un-

[26] Ethyl's patent structure and licensing systems were strikingly similar to that of the present defendants, in that a number of patents covering different stages of production of the products were involved, with the result that the restriction against sale to unlicensed jobbers could be characterized either as a restraint on alienation or else as a manufacturing restraint, depending on which patent was invoked by the patentee as the basis of its imposing the restriction. Like defendants here, Ethyl started out with a presumably lawful monopoly over the basic material—in Ethyl's case the monopoly was based on its tetraethyl lead patent. Ethyl then sold the tetraethyl lead (as Glaxo and ICI sell griseofulvin) to licensee refiners. Ethyl also had a product patent (like the Glaxo microsize griseofulvin patent) on "motor fuel produced by mixing gasoline [and tetraethyl lead]" and a use patent on the use of such fuel in car engines (*id.* at 446). As a result, the refiner who mixed tetraethyl lead with gasoline to produce high-test motor fuel and then sold the fuel to jobbers (1) "used and sold" tetraethyl lead, bringing himself within

lawful control over jobbers was established and maintained by resort to the licensing device, the decree entered by the district court "suppressed" its use completely, even though the license agreements "had been or might continue to be used for some lawful purposes" (*id.* at 461). The Supreme Court approved, and held (*ibid.*) that the district court had properly exercised its discretion in "disestablishing the licensing system."

The parallel between *Ethyl* and the instant case is clear. We need not and do not go so far here as the *Ethyl* court, and say that Glaxo's licensing system should be completely "suppressed" or "disestablished." But we do urge that this Court enjoin the defendants' well-entrenched program of keeping griseofulvin out of the hands of generic drug companies—whether the defendants effectuate this program by lawful or unlawful licensing practices.

The public purpose to be served by the decree in this case is to prevent defendants from suppressing generic drug sellers' competition in the sale of these drugs, and to pry that market open so that the public will enjoy the benefits of competition. To accomplish that purpose, it is necessary to prohibit defendants from employing any further bulk sales restrictions of any kind.

Conclusion

It has been shown that Glaxo and ICI refuse to sell bulk griseofulvin to generic drug manufacturers and other in-

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Ethyl's tetraethyl lead patent, and (2) "made and sold" the patented motor fuel, again, conduct coming under Ethyl's patents on the high-test fuel and its use.

In seeking to eliminate the restriction against sale of the patented high-test fuel, counsel for the government maintained that Ethyl's sale of the patented tetraethyl lead exhausted Ethyl's patent monopoly, so that Ethyl could not lawfully restrain the alienation of the gasoline-tetraethyl lead mixture (relying on *Adams v. Burke* and similar cases, cf. 302 F. Supp. at 10 & n. 43). Counsel for Ethyl argued, however, that the restraint against sale to unlicensed jobbers could be based on the other Ethyl patents covering the motor fuel mixture itself and its use, in which event the restraint arguably was capable of being characterized as a manufacturing restraint rather than a restraint on alienation (compare *Brief for the United States*, No. 536, O.T. 1939, pp. 50-58, with *Reply Brief for Appellants*, *id.*, pp. 6-9).

Apparently, defendants' counsel now adopt Ethyl's argument. The Supreme Court disregarded these doctrinal subtleties, in its *Ethyl* decision, and condemned the entire licensing program.

dependents. The defendants' licensees continue the prior pattern of conduct, established by the defendants' *per se* illegal agreements, and they too refuse to sell the drug to independents. At the same time, the defendants refuse to grant any licenses under the microsize patent, so that there is an absolute barricade against entry into the distribution of the commercially important form of the product. The present state of the market is such that generic drug makers and other independents are effectively foreclosed, and the public is denied the benefits of their competition.

It has also been shown that, in order to alter this state of the market, so that the effects of the defendants' past violations may be dissipated and the market that has been closed by the defendants' restraints may be pried open to competition, it is necessary that the decree in this case: (1) require bulk sale of griseofulvin on reasonable and nondiscriminatory terms, (2) require reasonable royalty licensing of griseofulvin patents and know-how, (3) require defendants to cease using any method of restraining bulk sales.

Finally, we have shown that the legal authorities fully support this Court's equitable power to enter such a decree.

For the foregoing reasons, it is submitted that the Court should enter a Final Judgment in the form proposed by the United States.

Respectfully submitted,

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Dated: July 7, 1970

APPENDIX A

JOHNSON & JOHNSON

Dr. W. O. Teeters
Dr. E. R. L. Gaughran
Mr. L. P. Prusak
New Brunswick, N. J.
November 30, 1958

Mr. H. P. Nack
Mr. G. F. Smith
Dr. John Henderson

Subject: "Griseofulvin"—Glaxo Laboratories, Ltd.—Schering

Memorandum to File

Following a meeting of the previous evening, Messrs. McKenzie and Lycan met on Saturday, November 29, with Messrs. Francis Brown of Schering, Robert Waterman of Schering, and A. E. Bide of Glaxo.

Mr. Bide stated the position of Glaxo and indicated that he now favors granting only the two licenses, one to Schering and the other to Johnson & Johnson. He restated his position of the previous evening that Glaxo will have to be impartial as between Schering and Johnson & Johnson. He suggested we might find it thus most convenient to work together since neither of us can gain an advantage under the circumstances.

After considerable discussion, we did tentatively agree on a joint program whereunder we would share in laboratory and clinical work. Arrangements were made for a meeting between Schering and Johnson & Johnson personnel next week to set up the program. In the meantime, Glaxo will ship "Griseofulvin" to Johnson & Johnson with the understanding it is to be shared with Schering.

Both Schering and J&J impressed on Mr. Bide that Glaxo cannot expect full pressure on promotion if further licenses are granted. Mr. Bide agreed, subject to approval by his Board at home.

The question of suppliers was discussed in detail. As reported by Mr. Bide, Mr. Brown objected strenuously to Merck. He pointed out that if Sharp & Dohme is not a licensee then Merck will press Glaxo continuously to permit general bulk sales. The position of Penick was reviewed and Schering advised that their experience with Penick on Prednisolone was excellent. Schering has auxiliary ex-

traction equipment and can help out, in fact, if Penick needs it. They also agreed with J&J that the secondary supplier can be Glaxo itself for the time being and until substantial sales volume is achieved.

The question of advantage was fully discussed. It is apparent that none can be anticipated. It was, therefore, agreed that Dr. Blank should refer to the drug by its generic name, "Griseofulvin," and then when asked about suppliers, he could say both Johnson & Johnson and Schering will have it under their own respective trade names.

It was agreed that we might very well come out at essentially the same time, if and when the drug is to be marketed. In effect, we will produce our N. D. A. application jointly. This may involve talking to F. D. A. and Welch in advance. Details are to be worked out at a meeting with Schering next week.

Mr. Bide agreed to resolve the question of suppliers, particularly Merck, in the United States, as quickly as practical. Meanwhile, Glaxo will rely on Schering and Johnson & Johnson to work out other details here. This includes arrangements for veterinary use. Schering vigorously opposed bringing in a third licensee even though limited to veterinary use. They point out they have ethical veterinary business and proprietary.

On division of supply in the United States, it was agreed that it would be on a 50-50 basis. If one or the other had extra needs or if one or the other had a surplus, the other would be expected to help out if practical but would not be required to do so.

/s/ W. H. Lycan
W. H. Lycan

PRE-HEARING BRIEF OF DEFENDANT ICI CONCERNING PROPOSED FINAL JUDGMENT, DATED DEC. 3, 1970

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, PLAINTIFF, v. GLAXO GROUP LIMITED AND IMPERIAL CHEMICAL INDUSTRIES LIMITED, DEFENDANTS	Civil Action No. 558-68

SIGMUND TIMBERG
Attorney for defendant
Imperial Chemical Industries Limited
815 15th Street N. W.
Washington, D. C. 20005

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United States v. *Loew's, Inc.*, 371 U. S. 38 (1962).....
United States v. *National Lead Co.*, 332 U. S. 319 (1947), *aff'g* 63 F. Supp. 513 (1945) .....

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United States v. *Syntex-Searle-Upjohn*, (D.D.C. Civil Action No. 478-68) (complaint filed February 23, 1968, dismissed for mootness October 15, 1968) .....

United States v. *Trans-Missouri Freight Association* 166 U. S. 290 (1897) .....

United States v. *United Shoe Machinery Co.*, 110 F. Supp. 295 (1953), *aff'd*, 347 U. S. 521 (1954).....

United States v. *United States Gypsum Co.*, 333 U. S. 364 (1948), 340 U. S. 76 (1950) .....

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, PLAINTIFF, v. GLAXO GROUP LIMITED AND IMPERIAL CHEMICAL INDUSTRIES LIMITED, DEFENDANTS	Civil Action No. 558-68

PRE-HEARING BRIEF OF DEFENDANT ICI
CONCERNING PROPOSED FINAL JUDGMENT

I. INJUNCTIVE RELIEF IN THIS CASE IS UNNECESSARY AND INAPPROPRATE, BECAUSE OF THE LIMITED NATURE OF THE VIOLATION INVOLVED, ITS LACK OF MARKET EFFECT AND THE IMPROBABILITY OF ITS RECURRENCE.

A. *Defendant ICI's general position on relief.*

The announced statutory purpose of equity antitrust relief, as stated on page 11 of plaintiff's Pre-Trial Brief, is to "prevent and restrain violations" of the Sherman Act (see 15 U.S.C. Sec. 4). In framing an appropriate Final Judgment, therefore, it is basic to have in mind the limited nature of the violation found by the Court. In the case of defendant ICI, the adjudicated violation was that it had, contrary to the rule laid down in the *Schwinn* case, restrained the alienation of bulk form griseofulvin by reserving in itself the power to control the resale of the bulk product (302 F. Supp. at 7-9).[1]

In ICI's view, the government's proposed form of Final Judgment goes far beyond anything necessary to "prevent and restrain" violations of the Act. ICI's position is a two-fold one:

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[1] This Court's written opinion dealt specifically with the bulk sale restriction found in ICI's agreement with its exclusive distributor, American Home Products Corporation ("Ayerst"). However, similar provisions were involved in the subsequent orders entered by Judge Sirica against Glaxo and by Judge McGuire against Glaxo and ICI.

(a) This Court should find, on the record, that the bulk resale restriction had been effectively and in good faith discontinued by ICI, and that there is no reasonable probability of its resumption in the future. In such event, on the precedent of the *W. T. Grant* and *Parke, Davis* cases, injunctive relief should not be awarded by the Court.

(b) At the most, even if the Court is persuaded that injunctive relief is necessary, such relief should take the form of a general injunction forbidding the restraint on alienation held to have violated the Act. Such an injunction should not be of broader scope than that decreed in the *Schwinn* and *Bayer-Chemagro* cases, which are discussed on pp. 38 to 41, below.

While this Court has ruled substantively that adjudication of the illegality of the bulk resale restriction is not moot, the question of relief stands on a different footing, see *United States* v. *Parke, Davis Co.*, 362 U. S. 29 (1960); *United States* v. *W. T. Grant Co.*, 345 U.S. 629 (1953). To obtain relief: —"the moving party must satisfy the Court that relief is needed—To be considered are the *bona fides* of the expressed intent to comply, the effectiveness of the discontinuance and, in some cases, the character of the past violations," see *United States* v. *W. T. Grant Co.*, 345 U. S. at 633.

As in the *Grant* case, this Court, on the record before it, "could decide that there was no significant threat of future violation and that there was no factual dispute about the existence of such a threat" (*ibid.*, p. 635), and consequently no need for injunctive relief. Thus, in the *Parke, Davis* case, the Trial Court, on the remand from the above-cited Supreme Court decision, found that "there is now no dangerous probability or even any reasonable probability or likelihood that the challenged action will, in the future, be resumed or undertaken by the defendant," see 1960 Trade Cases Para. 69, 776 (D.D.C.), and declined to enter an injunction against Parke, Davis.

In ICI's view, ICI's abandonment of the bulk resale restriction has been so complete and continuous as to "refute the Government's right to injunctive relief" against the restriction, see *United States* v. *Parke, Davis*

& Co., 362 U. S. at 49.[2] In support of its position that there is no occasion for decreeing injunctive relief against defendant ICI, ICI describes, in the next two sections of its brief:

> (a) the limited and unintentional nature of the violation found by the Court;
>
> (b) ICI's unqualified cancellation of the bulk resale restriction over three years ago;
>
> (c) the fact that, even prior to its cancellation, the bulk resale restriction was never operative and that it has never had any effect on the U. S. commercial griseofulvin market;
>
> (d) ICI's relinquishment, two years ago, of any influence or control over the U. S. griseofulvin market by licensing its dosage patent and in other ways; and
>
> (e) the absence of any reasonable probability that ICI will in the future seek to impose or enforce a bulk resale restriction.[3]

B. *Defendant ICI's cancellation of the bulk resale restriction and relinquishment of influence and control over the U. S. griseofulvin market.*

The *Grant* case specifies the *bona fides* and effectiveness of the discontinuance of the violation as two of the three elements determinative of whether injunctive relief is appropriate. On this score, the record shows that, even prior to the filing of the complaint in this case, ICI had relinquished all control over the activities of Ayerst, its U. S. distributor in selling pharmaceutical products on the U. S. market. It is now more than three years since ICI, in October, 1967, without referring to Glaxo, cancelled the bulk resale restriction, not only in the griseofulvin distribution agreement but in eight other drug distribution

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[2] This decision was cited by this Court as the precedent for its denial of defendant ICI's motion to dismiss the complaint against it as moot, see 302 F. Supp. at 8.

[3] Many of the facts brought out in these next two sections of this brief were cited in support of ICI's motion that the complaint against it be dismissed as moot. While ICI is loath to continue litigating a long-abandoned provision that it has no intention of reviving or reinstating, it notes that mootness is an appealable issue in this case.

agreements with Ayerst, its exclusive U. S. distributor (302 F. Supp. at 5, No. 13, and evidence therein cited). This cancellation took place only four months after the Supreme Court ruling in the *Schwinn* case, and four months before the filing of the Government's complaint. Concerning the Supreme Court ruling, the *Schwinn* District Court, on remand, said: "The law was not clear or certain, and only since the opinion of the Supreme Court [in *Schwinn*] has the law been clear enough for these defendants to act with certainty."[4] If ICI would so promptly and effectively terminate the bulk resale restriction merely on the basis of its distributor informing it of a pending government investigation, the inference is even more compelling that it would permanently desist from a practice adjudicated *per se* illegal by the Court.

Plaintiff has introduced no evidence challenging the *bona fides* of ICI's "expressed intent to comply" with the law since the cancellation of the bulk resale restriction, or "the effectiveness of the discontinuance" of the cancelled restriction.[5] On the other hand, ICI has on several occasions during the course of the trial, through interrogatory answers and affidavits, made it clear that its intention in cancelling the bulk resale restriction was to eliminate any restriction on the freedom of Ayerst to resell bulk supplies of pharmaceutical products (302 F. Supp. at 5, No. 14 and references therein cited; see references cited in Par. 11 of Bland Affidavit of November 25, 1970, reproduced herein as Appendix A and hereinafter referred to as the "Bland 1970 Affidavit").[6] Not only has it been stated to be ICI's policy not to influence or restrict in any way Ayerst's resale of bulk form griseofulvin, but the company's files were searched, first as of November 6, 1968 and then as of November 25, 1970, for all documents which related to ex-

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[4] 291 F. Supp. 567 at 568; see also this Court's reference to the "unpredictability" of the *Schwinn* ruling at 302 F. Supp. 9.

[5] This disposes of two of the three requirements that must be satisfied for the plaintiff to obtain injunctive relief, *United States* v. *W. T. Grant Co.*, p. 3, above.

[6] Because of the volume of documentation in this case and to assist the Court, the Bland 1970 Affidavit is not only addressed to factual matters raised by the plaintiff's present Pre-Hearing Brief, but also contains relevant references to, and updates, ICI's affidavits made during the earlier substantive phases of this proceeding.

pressions of interest, inquiries or requests for bulk sales of griseofulvin received by ICI, and no document was found which in any way indicated a purpose on the part of ICI to influence or restrict Ayerst's freedom to resell bulk form griseofulvin, or that the effect of the cancellation has been otherwise than to eliminate any restriction on such freedom (see Bland 1970 Affidavit, Pars. 12 and 13).

The adjudicated violation in this case related only to a restriction on the resale of bulk griseofulvin, and does not involve patents (see 302 F. Supp. at 9, fn. 40). Nevertheless, ICI has further demonstrated its "intent to comply" with the law and the "effectiveness of the discontinuance" of its past violation, by making its dosage patent generally available for licensing on reasonable terms and conditions and licensing it to five U.S. licensees (302 F. Supp at 5-6, No. 15; Pars. 9 and 10 of the Bland 1970 Affidavit), two of which have bought griseofulvin from Ayerst. Following on ICI's offer to grant licenses, inquiries were received by Ayerst which resulted in its quoting prices on bulk regular griseofulvin and dosage form microsize griseofulvin on some fifteen different occasions, and on bulk form microsize griseofulvin on seven or eight occasions. See Pars. 4, 5 and 6 of appended Affidavit of Maurice E. Silverstein, Vice President of Ayerst Laboratories Division, reproduced herein as Appendix B and hereinafter referred to as the "Ayerst Affidavit".

Since "the sole function of an action for injunction is to prevent future violations" and the plaintiff has not established that there is "a real threat of future violation or a contemporary violation of a nature likely to continue or recur" (*United States* v. *Oregon State Medical Society*, 343 U. S. 326, 333 (1952); see also *United States* v. *W. T. Grant Co.*, 345 U. S. 629, 633 (1953)), plaintiff should not be granted equitable relief.

C. *The nature of ICI's violation—and its lack of adverse effect on competition.*

We turn now to the character of ICI's violation, the third factor to be considered in deciding whether equity relief is warranted. The violation adjudicated by the Court was the reservation by ICI of the power to control Ayerst's resale of bulk griseofulvin supplied to it by ICI.

Despite the extension discovery had in this case, plaintiff

has failed to present any evidence that the power thus reserved to ICI was in fact exercised by ICI, so as to deprive any prospect of access to supplies of bulk form griseofulvin for the United States commercial market. In fact, Glaxo has vainly sought, through interrogatories propounded to plaintiff, to elicit from plaintiff any evidence that bulk sales would have been made but for the provision.

On the other hand, Ayerst's sworn affidavit (see Par. 3) is to the effect that it "had at no time prior to the deletion of this [bulk resale] clause in 1967 even received any inquires or requests from any company for commerical supplies of bulk griseofulvin for use in the United States. Ayerst had no occasion to consider making such a sale nor to ask ICI for consent to such a sale." As has been pointed out above, when Ayerst subsequently received requests for price quotations, it formulated its own independent policy in answering such requests, and has made some sales.

ICI itself had received no approaches from any U. S. company for supplies of bulk form griseofulvin for the commercial U. S. griseofulvin market.[7] Of eight requests for bulk form griseofulvin received from U. S. sources by ICI prior to its cancellation of the bulk resale restriction, five were for sales to take place in South America, Japan and countries other than the United States; one was for research purposes only; and one was for topical use, not the commercial oral use market. The eighth approach was from Allergan Pharmaceuticals, from the officers of which plaintiff took depositions in Los Angeles. It is clear from these depositions that the approach was made by a junior employee of that firm acting entirely on his own account and that Allergan had no interest in purchasing bulk griseofulvin or entering the dosage form griseofulvin market (see Par. 14 of Bland 1970 Affidavit; Bland Affidavit of November 29, 1968; depositions of Calvin Herbert, Jr., pp. 9-10, Eric L. Nelson, pp. 7-10, and E. J. Browning, pp. 7-10).

Plaintiff also took depositions, and filed in the record letters, from the officers of Abbott Laboratories, who stated unqualifiedly that they were not interested in entering the

[7] ICI has set forth, in response to plaintiff's Motion to Produce and in its answer to plaintiff's Interrogatory No. 67, the documents and information in its files relating to all approaches made to it by any U.S. company for supplies of bulk griseofulvin.

small and highly competitive griseofulvin market (see deposition of Marlin T. Leffler, pp. 22-23; GX 51; GX 55).

The reason why companies such as Abbott and Allergan were not interested in entering the U. S. griseofulvin market had nothing to do with the bulk resale restriction, but related to the griseofulvin market situation. Plaintiff's own discovery shows that responsible pharmaceutical executives had dismissed the idea of entering the griseofulvin market because of its small size and prior occupation by three vigorous and established competitors. The record shows that the U. S. market for griseofulvin is a declining, not an expanding, one (see Par. 8 of Ayerst Affidavit). It also shows, contrary to the impression sought to be conveyed in plaintiff's Pre-Trial Brief, that there was price competition in the griseofulvin market at both wholesale and retail levels, and that market shares of the three competitors fluctuated over the years (see ICI's and Glaxo's Answers to Plaintiff's Interrogatory Nos. 42(c) and 43; Pars. 8, 9 and 10 of Bland 1970 Affidavit; Bland Affidavit of November 26, 1968).

In summary, there is no evidence that the bulk resale restriction had an adverse effect on competition. The plaintiff's glib generalization that Ayerst and Glaxo's vendees were buying griseofulvin "packaged in a competition-free wrapping" (see p. 7, fn. 7) is belied by the demonstrated existence of price and sales competition. Since the bulk resale restriction had no demonstrable adverse effect on competition, there is no "competitive evil" requiring to be dissipated by injunctive relief.[8]

II. PLAINTIFF'S PROPOSED FINAL JUDGMENT CANNOT BE JUSTIFIED ON EITHER LEGAL OR ECONOMIC GROUNDS

A. *Introduction*

In this section of its brief, defendant ICI will discuss the following major respects in which plaintiff's proposed Final Judgment is inappropriate:—

(1) It would require the sale by ICI of bulk griseofulvin to all applicants.

[8] The lack of either legal or economic justification for the far-reaching compulsory sale and compulsory patent and know-how licensing requested by the Government is further dealt with in the next Part of this Brief.

(2) It would require the licensing by ICI of its griseofulvin patents (which it has already done) and of its technical data.

(3) Assuming *arguendo* that some form of injunction is deemed appropriate by the Court, the other injunctive relief proposed by the plaintiff covers matters having no connection with the subject matter of this proceeding.

(4) On the same assumption as in (3) immediately preceding, relief broader than that awarded in the *Schwinn* case and the Government's related *Bayer-Chemagro* suit would be inappropriate here.

By way of general preface to the discussion which follows, defendant ICI regards plaintiff's Pre-Hearing Brief as a tour de force having nothing to do with the facts of the instant case. ICI does not dispute most of the legal generalizations with which plaintiff's Brief abounds, but it strongly questions their relevance to this record, which plaintiff by and large ignores and on a few occasions misstates. If ICI's Brief makes duller reading than some of plaintiff's flights of rhetoric and abstract innuendoes concerning antitrust defendants' propensities for evil doing, it is because ICI's Brief is anchored to the bedrick of the record of this case and the realities of the griseofulvin market.

B. *Plaintiff's proposed compulsory sale relief.*

Plaintiff's basic legal argument for compulsory sale relief is that it is necessary to "pry open" the griseofulvin market to competition (see pp. 2, 12, 13 and 15 of its Pre-Hearing Brief). That argument rests on the unsupported and erroneous factual premise that the bulk resale restriction had the effect of foreclosing the market to competitors. As already shown (see pp. 5 to 10, above), this premise is not supported by the record, which indicates the contrary —that the bulk resale restriction had no such adverse competitive effect and that the U. S. griseofulvin market is in fact competitive.

The three cases relied on by plaintiff to support its request for compulsory sale relief are distinguishable from this case with respect to both their facts and the legal issues involved.

These cases involve situations in which lengthy records showed that trade had been monopolized and competitors foreclosed from the market by industry-wide leasing and patent practices that were imposed and enforced by dominant firms. They can therefore have no application to a single unenforced and long-abandoned contractual provision restraining alienation, having no anti-competitive impact, such as is involved in this case.

Thus, in *United States* v. *United Shoe Machinery Co.*, 110 F. Supp. 295 (D. Mass. 1953), *aff'd* 347 U.S. 521 (1954), United's refusal to sell, and its lease-only system of distributing, its important machines was at the heart of the holding that it had illegally monopolized the shoe machinery business of the United States in violation of Section 2 of the Sherman Act.[9] With the United Shoe's illegal monopoly so clearly based on vices in its lease-only system of distribution, it was only natural for the Court to provide by way of relief that United Shoe give its lessees the additional option to purchase the machines; the remedy was a clear antidote to a proven competitive evil.

Besser Mfg. Co. v. *United States*, 343 U.S. 444 (1952), is similarly inapplicable to the present situation. Unlike the present case, Besser's offense had been to violate Section 2 of the Sherman Act; it had illegally monopolized the production of machinery for making concrete blocks, especially the most efficient type. The evidence was that it had refused to sell these machines and had insisted on leasing them, despite the desire of some users to purchase the machines, and was able, because of its illegal monopoly power, to charge four times as much under its lease agreement as it would if the machine had been bought (see pp. 64-68 of the Brief for The United States in the Supreme Court). Because of Besser's monopoly power, the Supreme

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[9] The ways in which United Shoe's lease-only system had built up its illegal and exclusionary monopoly power were thus summarized in the detailed opinion of the District Court:

"Much of United's market power is traceable to the magnetic ties inherent in its system of leasing, and not selling its more important machines. The lease-only system of distributing complicated machines has many 'partnership' aspects, and it has exclusionary features such as the 10-year term, the full capacity clause, the return charges, and the failure to segregate service charges from machine charges. Moreover, the leasing system has aided United in maintaining a pricing system which discriminates between machine types" (*ibid*, at p. 344).

Court upheld an option, limited to *existing* lessees of machines, to purchase the leased machines on terms mutually satisfactory to the parties concerned.

The third of the three cases cited by plaintiff, *International Salt Company* v. *United States,* 332 U. S. 392 (1947) (see pp. 15-17 of its Brief), is completely inapposite. This case involved an illegal tie-in; International Salt had leased its patented salt-dispensing machines on condition that its lessees buy salt for use in the machines exclusively from it. The Final Judgment required International Salt "to offer to lease *or* sell *or* license the use" (underscoring supplied) of the salt-dispensing machines "on non-discriminatory terms and conditions." The lessee was not given an option to buy. The only issue on the Supreme Court appeal was International Salt's argument that it should not be held to the requirement of distributing its machines on non-discriminatory terms. The reason for requiring non-discriminatory terms of distribution, which was upheld by the Supreme Court, was directly related by the Government to the illegal tie-in practice—

> "that to compel appellant to observe uniformity of price for its machines removes any temptation for more favorable treatment of a customer who buys its salt" (see dissenting opinion of Mr. Justice Frankfurther, at p. 403).

Plaintiff's view of the griseofulvin market as one that has been monopolized by virtue of the bulk sale restriction has been shown to be fallacious (see pp. 5 to 10, above), and its alleged legal precedents to be inapplicable to the present facts (see pp. 13 to 15, above). In the light of these factors, it is perhaps anticlimactic to point out other reasons why the award of compulsory sale relief against ICI is inappropriate.

In the first place, ICI has by contract appointed Ayerst as its exclusive U. S. distributor of griseofulvin, for reasons stated in the Bland 1970 Affidavit, Par. 3. The legality of this exclusive distributorship commitment is not challenged, and there are sound business reasons for ICI (which has no pharmaceutical selling organization in the United States and produces a limited number of drug products suitable for marketing in the United States) thus entrusting sales in the U. S. drug market to a long-established

and well-staffed U. S. firm (Par. 3 of Bland 1970 Affidavit). It would be financially prohibitive and economically impossible for ICI to duplicate in the United States the kind of organization needed to develop the U. S. drug market (see Pars. 9 and 10 of the Ayerst Affidavit for the wide range of functions and size of staff needed to operate commercially in the United States) in order itself to make griseofulvin available. Accordingly, plaintiff's proposed compulsory sale relief should not be considered by the Court, because it would entail the partial abrogation of ICI's completely legal and economically sound exclusive distributorship relationship with Ayerst.

It should also be borne in mind that ICI must supply the needs of purchasers located in the U.K. and over a hundred other countries. ICI periodically encounters difficulties in supplying this world-wide demand from its limited facilities (Bland 1970 Affidavit, Par. 4). For a U. S. court to impose a compulsory sale obligation on a British firm, which produces a commodity in the U.K. from which it must satisfy the demand of the 100 countries other than the U. S., is manifestly unfair and harsh from a practical standpoint.

From a legal standpoint, the compulsory sale injunction would involve the extension of this Court's jurisdiction into the business activities of a British company carried on within the United Kingdom. This is true not only of ICI's manufacture of griseofulvin, but its subsequent export operations. ICI ships bulk griseofulvin f.o.b. U. K. port to Ayerst. Once the griseofulvin leaves the U. K. port, ICI has no further involvement in the U. S. marketing of the product (see Par. 7 of Bland 1970 Affidavit). Thus, plaintiff's requested compulsory sales injunction involves an extraterritorial reach of jurisdiction which raises issues of an exceedingly delicate nature and should not be considered by this Court, especially where it is so clear that there is no compelling need for such relief.[10]

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[10] See *United States* v. *Holophane Co.*, 352 U.S. 903 (1956), *aff'g by an equally divided vote*, 119 F. Supp. 114 (S.D. Ohio 1954). Section XI of the Final Judgment in this case ordered a *United States* company, which was a party to an international cartel agreement under which it agreed not to *export from the United States* to territories of its British and French cartel partners, to promote *export sale from the United States* and "*to use reasonable efforts* to promote the sale and distribution of its products in foreign markets" (underscoring supplied), see 1954 Trade Cases, para. 67, 679. This provisions was

Having shown that a compulsory sale injunction of any kind is inappropriate in this case, it is not necessary to deal with the plaintiff's subordinate proposition that ICI be required to sell bulk griseofulvin *at the same price* to the generic and mail order houses at it does to Ayerst. However, since plaintiff has filed three lengthy industry affidavits purporting to support this latter proposition, defendant ICI believes it may be helpful to the Court to indicate how unsubstantiated, conclusory and speculative are the economic premises upon which these affidavits rest. Of course, plaintiff is a long way from showing how this specific item of relief relates to the violation in this case.

The affidavits in question are supplied by three generic houses, the entire business of which consists of "buying antibiotics in bulk, converting them into dosage form,[11] and selling the packaged product to other pharmaceutical companies which distribute the finished packaged product." By way of contrast, Ayerst has for years invested money, time and research in developing a nationwide market for griseofulvin; arranged for the extensive animal and human pharmacology, toxicology and broad clinical testing and evaluation needed to obtain and maintain Food and Drug Administration approval for the drug; supported a staff that has informed the medical profession concerning the uses, efficacy, safety and side effects of the drug; paid tariff duties and arranged for customs clearance of the bulk product; paid patent royalties; assayed the bulk form of the drug; arranged for its micronization; processed the bulk griseofulvin into dosage form; certified the micronized bulk drug, and re-certified the dosage form, to the Food and Drug Administration; and arranged for warehousing and national distribution (see Pars. 9 and 10 of Ayerst Affidavit).

The generic houses, by their own affidavits, spend on advertising only 5% to 8% of what is spent by major brand companies such as Ayerst (see Par. 2 of Biocraft Affidavit),

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attacked in the Supreme Court on international law grounds, and escaped being overturned only by an equally divided vote of that Court. There is no sound factual or legal basis for an order such as that requested by the plaintiff which would compel a *British* company to *export from abroad into the United States.*

[11] See Biocraft Affidavit, Par. 2. It is not clear whether Dooner Laboratories has any tableting or encapsulating facilities; Zenith and Biocraft state they have.

and have six or nine people on their sales staffs (see Par. 3 of Dooner Affidavit).[12] This may be contrasted with Ayerst's 450 medical detail men, not to mention its 400 scientists and technicians (see Par 10 of Ayerst Affidavit). The generic houses have no connection with the marketing of any drug until the long experimental scientific and commercial periods have passed and it has been safely launched and established on the market by entrepreneurs such as Ayerst.[13] The suggestion that ICI must sell the bulk griseofulvin to the generic houses at the same price as it does to Ayerst, its exclusive distributor, and must ignore Ayerst's heavy and continuing investment and costs, is as startling as it is unreasonable.

Before pointing out the respects in which the industry affidavits do not support (and, in fact, even contradict) what plaintiff asserts in its Brief, it is necessary to correct the totally misleading impression that both the Brief and the affidavits give as to the availability of griseofulvin from Ayerst. Thus, Zenith mistakenly indicates that Ayerst has not been willing to sell bulk griseofulvin in microsize form (see Par. 8 of Zenith Affidavit) and plaintiff's Pre-Hearing Brief (see p. 8) uncritically accepts this as the fact. The actual state of affairs is that Ayerst has made some seven or eight quotations on bulk microsize griseofulvin, and has agreed to supply experimental quantities of such material for testing to two companies indicating an interest in its purchase (Par. 6 of Ayerst Affidavit).

Zenith admits that it "presently purchases the antibiotic griseofulvin microsize in finished capsules from Ayerst" (Par. 5 of Zenith Affidavit of May 27, 1970), but complains that it has been able to make only a few sales (*ibid*, par. 11). Despite its complaint, Zenith, in addition to the 500,000 capsules of 250 mg. microsize griseofulvin purchased by it before its affidavit was executed, put in a repeat order for another 500,000 capsules on October 9, 1970, *after that filing*. In addition, Ayerst has sold one million capsules

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[12] Zenith's Affidavit does not indicate the number of its employees, the volume of its sales or the scale of its operations. Biocraft recites that it has approximately 26 employees *in toto* (Par. 2 of Biocraft Affidavit).

[13] Ayerst has now been importing griseofulvin for more than eight years (see Par. 2 of Ayerst Affidavit).

(250 mg.) of microsize griseofulvin to Owen Laboratories,[14] and has quoted prices on bulk regular and dosage form microsize griseofulvin to some fifteen inquiries (Pars. 4 and 5 of Ayerst Affidavit).

The foregoing would appear to be clear evidence that (a) supplies of microsize griseofulvin, both bulk and dosage form, are available at commercially viable prices, within the framework of the existing ICI-Ayerst exclusive distributorship relation, and that (b) the generic houses do not require, as the plaintiff so unreasonably urges, access to ICI's bulk griseofulvin at the same price as is paid by Ayerst.

In support of its proposal that ICI sell to Ayerst and the generic houses at the same price, plaintiff relies on the assertion that the price quoted by Ayerst is so high that a generic or private label house "cannot possibly market the drug" and that the margin "is squeezed to zero or negligibly thin" (see page 9 of plaintiff's Pre-Hearing Brief). But this exaggerated claim by plaintiff's counsel is a far cry from what the affidavits of the businessmen say. Zenith merely recites, conclusorily, that, if the bulk product were available to it, "we believe that Zenith could make substantial sales of the griseofulvin microsize capsules that it would manufacture at a reasonable profit" (Zenith Affidavit, Par. 12).

Turning to the Dooner Affidavit, one of the letters attached to that affidavit (Exhibit 5) says, with reference to an agreement by a U. S. licensee (presumably Ayerst) to sell bulk griseofulvin to it, merely that "the price quoted is *a bit higher* than the price on a direct basis from Glaxo or ICI" (underscoring supplied). This is a perfectly understandable business ploy by a purchaser seeking a better price from a vendor, but it falls far short of the price squeeze hypothesized by the Government in its Brief.

The only affidavit that makes any pretense of buttressing by specific figures the proposition that the generic house will suffer a price squeeze if not allowed to purchase griseofulvin direct from Glaxo or ICI is that of Biocraft, but its supporting statistics are inaccurate. After some ir-

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[14] Among the reasons why a purchaser of griseofulvin for resale to the commercial market might prefer to buy the product in dosage form is the resulting saving of the time and expense involved in satisfying the Food and Drug Administration as to the safety and efficacy of its processing operations (see Par. 7 of Ayerst Affidavit).

relevant discussion on the pricing of penicillin, the Biocraft Affidavit emerges with two propositions (see Par. 10 of said Affidavit):

(a) Ayerst's alleged dosage form price of $50 per thousand of 250 mg. capsules "requires" Biocraft to sell to a distributor at a price of $84 per thousand, and leaves the distributor with a spread of only 25% of the retail price, i.e. $112 per thousand.

(b) This spread, according to the Affidavit, is too low for the distributor, who "requires" a 33⅓% spread of the retail price.

Contrary to Biocraft's statements, Ayerst's dosage form price is $46.30 (not $50) per 1,000 (Ayerst Affidavit, Par. 5). Moreover, Biocraft mistakenly assumes that it (rather than Ayerst) has to pay a $4 royalty to ICI per 1,000 capsules (Ayerst Affidavit, Par. 7). Accordingly, correcting Biocraft's erroneous figures but assuming *arguendo* that Biocraft is "entitled" to a $30 markup on its purchase price for merely rebottling the drug and shipping it to a distributor, we find that Biocraft is in a position to sell the capsules to a distributor at $76.30 per 1,000, which would give the distributor a 32% spread of the retail price —a rather close approximation to the 33⅓ taken out of the air by Biocraft.

Plaintiff's proposition that a certain percentage of markup is "required" or appropriate rests, not on any analysis of market factors, but on the self-serving and uncorrobated *ipse dixits* of the generic houses. There is, of couse, no accepted basis for determining what is a proper markup for either a generic house or its distributor-vendee. The ease with which interested parties can frame self-serving generalizations is further illustrated by Biocraft's bland assertion that it can obtain 10% of the market and $1 million of annual sales in a market assiduously developed over the years by three competitive concerns (see Pars. 2 and 6 of Biocraft Affidavit). It may be noted that market survey figures indicate total 1969 griseofulvin sales of $6,712,000 (Par. 8 of Ayerst Affidavit), as contrasted with Biocraft's assumed $10 million of sales. Biocraft's rosy prediction of gaining $1,000,000 annual sales should be matched against the fact that its *total* sales of *all* products distributed by it are stated by it to be $2.6 million, and that Ayerst, after

eight years in the griseofulvin market, has only $1.6 million of sales.

In the final analysis, the real lesson to be drawn from the foregoing analysis is not so much that plaintiff's statistics are inaccurate and non-probative, but that it is inappropriate for any court to be put into the business of fixing prices for an industry, or determining margins of profit as between different classes of vendors performing incommensurable and completely disparate services in the distribution process. Such a non-judicial burden is particularly inappropriate where, as here, there is no legal justification for its assumption and the only material before the Court consists of conclusionary, self-serving and unsubstantiated statements by parties who would benefit from the Court's price and margin fixing activity.

C. *Plaintiff's proposed patent and know-how licensing relief.*

Plaintiff's request for compulsory patent and know-how licensing relief is grounded on the proposition that, in cases

> "in which defendants' violation of the Sherman Act has been grounded on their use of the monopoly power conferred by their patents, the courts have customarily decreed reasonable royalty licensing, in order to pry the market open to newcomers" (p. 21 of plaintiff's Pre-Trial Brief).

Yet, plaintiff points to no finding or holding by this Court that either ICI's or Glaxo's patents have been in any way misused. Nor can it point to any such ruling, for this Court has clearly stated (302 F. Supp. 1 at 9, fn. 40) that:

> "The case has not been characterized as a patent misuse, patent licensing or know-how licensing problem. See Note 16, *Supra* and Note 43, *Infra.*"

This case involves a restraint on alienation, not an abuse of patent monopoly power. Moreover, this brief has already shown that there exists here no market that needs to be pried open to newcomers (pp. 6 to 10, 18 to 23, above). Accordingly, the cases relied on by plaintiff for compulsory patent licensing relief have no relevance here.

To take plaintiff's cases in chronological order, in *Hart-*

ford Empire v. *United States*, 323 U. S. 386, 417 (1945), *clarified*, 324 U. S. 570 (1945), where the trial lasted 112 days, the printed record ran to 16,500 pages and the Court's opinion to 160 pages, the charge was that:

> "all the defendants agreed, conspired, and combined to monopolize, and did monopolize and restrain interstate and foreign commerce by acquiring patents covering the manufacture of glass-making machinery, and by excluding others from a fair opportunity freely to engage in commerce in such machinery and in the manufacture and distribution of glass products. *The gravamen of the case is that the defendants have cooperated in obtaining and licensing patents covering glass-making machinery, have limited and restricted the use of the patented machinery by a network of agreements, and have maintained prices for unpatented glassware*" (332 U.S. at 392; underscoring supplied).

In *United States* v. *National Lead Co.*, 332 U. S. 319 (1947), *aff'g* 63 F. Supp. 513 (S.D.N.Y. 1945), the Court was dealing with an illegal international cartel to divide world markets for the sale of titanium pigments, based on patent exchanges and licenses involving the leading U. S. and foreign producers of such pigments. After describing in detail the illegal restraints of domestic and international trade imposed by the defendants' licensing arrangements, the District Court thus listed the patent licensing abuses involved (see 63 F. Supp. at 523-4):—

> "The system of territorial allocation and suppression of trans-Atlantic traffic in titanium compounds and pigments cannot be justified as ancillary to the grant of a license under a patent. True the network of agreements did involve cross licensing of patents—but it was not limited thereto. The agreements applied to patents not yet issued and to inventions not yet imagined. They applied to commerce beyond the scope of any patents. They extended to a time beyond the duration of any then-existing patent. Ethyl Gasoline Corporation v. United States, 1940, 309 U. S. 436, 456, 60 S.Ct. 618, 84 L.Ed. 852. They embraced acknowledgement of patent validity with respect to patents not yet issued nor applied for, and concerning inventions not yet conceived. Pope Mfg. Co. v. Gormully, 1892,

144 U. S. 224, 12 S. Ct. 632, 36 L. Ed. 414; United States v. Hartford-Empire Co., D.C.N.D. Ohio, 1942, 46 F. Supp. 541, 615. They extended to countries, such as China, where no system of patent monopolies exists. Interstate Circuit, Inc. v. United States, 1939, 306 U. S. 208, 59 S. Ct. 467, 83 L. Ed. 610. They regulated the disposition of the products after sale by the licensees. United States v. Univis Lens Co., 1942, 316 U. S. 241, 62 S. Ct. 1088, 86 L. Ed. 1408; United States v. Bausch & Lomb Optical Co., 1944, 321 U. S. 707, 64 S. Ct. 805 L. Ed. 1024."

In *United States* v. *U. S. Gypsum Co.*, 340 U. S. 76 (1950), the Supreme Court's approval of compulsory patent licensing relief was based on a trial record that was replete with indications of patent licensing abuse. The following quotations from the Court's opinion (at p. 83) make this clear:

"In our [prior] opinion, 333 U. S. 364, 389, we said that

'the industry-wide license agreements, entered into with knowledge on the part of licensor and licensees of the adherence of others, with the control over prices and methods of distribution through the agreements and the bulletins, were sufficient to establish a prima facie case of conspiracy!

We said that the intention of United States Gypsum and its licensees to act in concert to attain the purpose of the conspiracy, restraint of trade and monopoly, was apparent from the face of the license agreements. Pp. 389, 400.

'The licensor was to fix minimum prices binding both on itself and its licensees; the royalty was to be measured by a percentage of the value of all gypsum products, patented or unpatented; the license could not be transferred without the licensor's consent; the licensee opened its books of accounts to the licensor; the licensee was protected against competition with more favorable licensees and there was a cancellation clause for failure to live up to the arrangements.' "

In *Besser Mfg. Co.* v. *United States*, 343 U. S. 444 (1952), the defendants had been charged with conspiring to restrain

and monopolize interstate commerce in block-making machinery in violation of Sections 1 and 2 of the Sherman Act, and with attempting to monopolize the industry in violation of Section 2 of the Act. The Supreme Court found that "appellants sought to eliminate competition through outright purchase of competitors and strict patent-licensing arrangements with the Stearns Company and the patent owners, Gelbman and Andrus", and that the defendants had demonstrated "a penchant for abuses of patent rights," *ibid.* pp. 447, 449.

The cases relied on by plaintiff thus indicate on their face that compulsory patent licensing is appropriate only in cases where industry-wide patent misuse is involved, and is not appropriate in a case involving a simple (and long terminated) restraint on alienation. Lacking any basis in the record for compulsory patent licensing relief, it follows that there is no economic or legal basis in the record for compulsory disclosure of technical information, the availability of which is not an independent matter but is intended "to accompany patent licenses in this field," *U. S.* v. *National Lead Co.*, 332 U. S. at 355 (see, in accord, p. 23 of plaintiff's Pre-Trial Brief).[15]

Plaintiff's arguments for compulsory patent licensing relief are directed primarily to the Glaxo microsize patent, and to the argument that compulsory licensing under that patent is necessary in the event that defendants should elect no longer to sell in the U. S. (p. 18 of plaintiff's Pre-Hearing Brief). ICI leaves to Glaxo the task of dealing with this argument in detail, but it cannot forbear from making two observations. First, plaintiff supplies not the slightest indication of why either defendant should stop making sales into and cease deriving profits from a market which both have been supplying for over eight years.

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[15] As in the case of patent relief, the award of know-how relief against ICI requested by plaintiff would be an empty gesture, and is therefore inappropriate on that score as well. The generic houses are already performing their own tableting or encapsulating (see Par. 4 of Zenith Affidavit and Par. 3 of Biocraft Affidavit) or would have other U.S. firms perform that operation for them; therefore, no know-how from ICI is required in connection with practising the ICI dosage patent. Such grinding of coarse particles into microsize griseofulvin as ICI performs in the United Kingdom involves the use of a different process than that employed by Ayerst in the U.S. and has not received any new drug approval from the Food and Drug Administration (Par. 6 of Bland 1970 Affidavit).

Second, on the general principle that water can rise no higher than its source, plaintiff's failure to establish that it is entitled to compulsory sale relief carries down with it the ancillary and derivative proposition that it is entitled to compulsory patent licensing relief.

With respect to ICI's single patent, plaintiff says (at p. 19 of its Brief) :—

> "We may assume that ICI's objection to a decree respecting granting licenses under its patent is primarily a matter of principle, for ICI has already assured the Court that it would and has granted non-exclusive licenses under the ICI patent, on reasonable terms and conditions (see 302 F. Supp. at 5-6)."

ICI has, as indicated by plaintiff, given notice of the general availability of its single patent for licensing on reasonable terms and conditions. Having granted such licenses to five U. S. companies (see Pars. 15 and 16 of Bland 1970 Affidavit), two of which have bought griseofulvin from Ayerst (see Par. 4 of Ayerst Affidavit), *further patent relief against ICI is not needed and should not* be awarded by the Court on that ground, as well as because of the lack of economic and legal justification in the record for patent relief of any kind.

D. *The inappropriateness of injunctive relief covering (1) non-drug products and (2) patent manufacturing licenses.*

Defendant ICI has set forth in Part I of this Brief the reasons why no injunction should issue in this case. Should the Court nevertheless be persuaded that an injunction against the bulk resale restriction is appropriate, the limited nature of the violation and its lack of any operative, much less anti-competitive, effect indicates that this Court, in its discretion, could well limit the scope of the injunction to the single commodity with which this case is concerned—griseofulvin. *However, since ICI has no intention of imposing or enforcing bulk resale restrictions with respect to any drug, it would not object to an injunction applicable to drugs generally.*

But plaintiff's proposed Final Judgment has (perhaps unwittingly) defined "drugs" in such a way as to include products that are not in the drug field at all. As is more

fully set forth in Par. 19 of the Bland 1970 Affidavit and the schedule attached thereto, Section I(C) of plaintiff's proposed judgment, in defining drug to include "any intermediate therefor [i.e., for a drug], and any product for which such drug is an intermediate," includes products completely outside the pharmaceutical realm, such as dyestuffs, insecticides, plastics and explosives. Plaintiff's intention to cover the drug field would be fulfilled if the above-quoted language were stricken and the proposed Section I(C) were to read:—

> "(C) 'Drug' shall be defined as it is in 21 U.S.C. § 321 (g)(i); and such term shall also include any form of such drug (bulk, dosage form or otherwise)."

In ICI's view, an injunction comprehensively prohibiting it from imposing any restriction on the resale of any drug bought from it would apply regardless of whether the drug in question was patented, or whether ICI's vendees were licensed under an ICI product, process or use patent. ICI does *not* argue, as erroneously stated on page 26 of plaintiff's Pre-Hearing Brief, that it is legitimate for it to prevent Ayerst from reselling bulk griseofulvin because Ayerst has been licensed by it, under the Glaxo patent, to convert regular size bulk griseofulvin into microsize griseofulvin.[16]

Even the most broadly conceived injunction against restrictions on the resale of a bulk drug does not reach the situation involved in a pure manufacturing license, which [may be defined] as one where the licensee is licensed under a product or process patent applicable to a material or product and the licensor (such as ICI) is *not* involved in supplying that material or product to the licensee. It is ICI's position that such pure manufacturing licenses should not be covered in any injunction decreed by this Court, because such licensing arrangements bear no relation to the

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[16] Similarly, plaintiff's lengthy analysis of the *Ethyl* case, 309 U.S. 436 (1940) (see pp. 32-34 of its Pre-Hearing Brief)is irrelevant and misdirected, and should therefore be ignored by the Court. The reason is that ICI is rejecting, not adopting, Ethyl's argument that a restraint on the alienation of Ethyl's tetraethyl lead is justified because Ethyl's vendees are licensed under Ethyl's product patent on motor fuel produced by mixing gasoline and tetraethyl lead, and under Ethyl's use patent on the use of such motor fuel in car engines.

violation found in this case or the remedy for that violation.[17] The Antitrust Division has recognized the legal difference between restrictions imposed on licensee-vendees, on the one hand, and restrictions imposed on manufacturing licensees, on the other. Public statements by two of the Division's leading officials indicate that the Antitrust Division has brought different cases to test the validity of these two different kinds of restrictions, and that it recognizes that the present case was not brought to test manufacturing license arrangements embodying bulk sale restrictions.[18] It is significant that both of the cases cited by Assistant Attorney General McLaren as test cases for attacking bulk sale restrictions in manufacturing licenses have been dismissed with prejudice.[19] It would be ironic indeed if ICI were subjected to injunctive relief on a matter unrelated to the violation of which it was found guilty, and which the plaintiff has for more than two and a half years been vainly endeavoring to establish as illegal.

With characteristic excessive suspiciousness, plaintiff conjures up a hypothetical situation in which Glaxo would cease supplying Schering and Johnson & Johnson with bulk griseofulvin, would have those companies buy griseofulvin in bulk from third party suppliers, and would then justify imposing a bulk sale restriction on Schering and Johnson & Johnson by licensing its patents to them (see pages 24-25 of plaintiff's Pre-Trial Brief). Plaintiff does not ascribe

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[17] ICI takes no position as to the legality or desirability of any bulk sale or other restrictions in pure manufacturing license arrangements, and sees no occasion for involving the Court in any inquiry as to such legality or desirability.

[18] See addresses of Assistant Attorney General Richard W. McLaren, "Patent Licenses and Antitrust Considerations," delivered to the PTC Research Institute of George Washington University, June 5, 1969, p. 5 (reported at 5 CCH Trade Regulation Reporter, par. 50,246), and address of Roland W. Donnem, Director of Policy Planning, "The Antitrust Attack on Restrictive Patent License Provisions," Detroit, Michigan, September 25, 1969 (reported at 5 CCH Trade Regulation Reporter, Par. 50,260).

[19] As the Court knows from earlier arguments and papers in this cause, one of these cases, *United States* v. *Syntex-Searle-Upjohn*, Civ. 478-68, an action brought in this district, was dismissed on account of mootness. The other case, *United States* v. *Sterling Drug Inc.*, (D.N.J. Civ. 175-68), which was filed on February 23, 1968, was dismissed with prejudice on November 5, 1970, after proceedings taking up nine pages of docket entries (see Appendix C for certificated copies of the Stipulation of Dismissal and the last page of docket entries).

this type of deviousness and naivete to ICI, possibly because it is aware of ICI's offer, at the outset of this litigation, to stipulate that ICI will not at any time revive or reinstate any restriction on bulk sales with respect to the products covered by the nine agreements from which the bulk sale restriction had been deleted.[20] The notion that ICI would cease selling any of these drugs and shift to a manufacturing license arrangement is a truly far-fetched one, since ICI obtains far larger profits from selling drugs than it *would* from licensing patents on the drugs (see Par. 17 of Bland 1970 Affidavit). While ICI stands ready to confirm the prior commitment undertaken by Mr. Hoare, if deemed desirable by the Court, this should not be necessary, because it would be commercial stupidity for ICI to abandon the bulk griseofulvin market and the commercial profits in supplying that market for the purpose of asserting a legal right that is of no monetary value to it.[21]

All of the cases relied on by plaintiff involve relief that is co-extensive with the violations and the practices of the defendants, as found in the trial record by the Trial Judge. This is not true of the injunctive relief requested by the plaintiff with respect to manufacturing patent license arrangements, which are not involved in any way in the pending litigation and which the Antitrust Division has recognized are not so involved. Therefore, the plaintiff's cases are inapplicable.

For example, *United States* v. *Trans-Missouri Freight Association*, 166 U. S. 290, 308 (1897), involved railroads that had participated in an Association which had by joint action maintained rules, regulations and rates for carrying freight over their respective lines. After the judgment of the Trial Court but before the Supreme Court's decision on the appeal, the Association had been dissolved. The defendants asked that the appeal be dismissed because the Association had been dissolved. In disagreeing with defendant's argument, the Supreme Court said (at p. 308):

"If the injunction were limited to the prevention of

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[20] See Par. 8 of Affidavit of Reginald George Hoare, Chairman of ICI's Pharmaceutical Division, executed May 16, 1968.

[21] Incidentally, plaintiff's hypothetical postulates an availability of bulk griseofulvin from sources other than ICI and Glaxo that suggests that compulsory sale relief against ICI and Glaxo is not necessary.

> any action by the defendants under the particular agreement set out, or if the judgment were to be limited to the dissolution of the association mentioned in the bill, the relief obtained would be totally inadequate to the necessities of the occasion, provided an agreement of that nature were determined to be illegal. The injunction should go further, and enjoin defendants from entering into or acting under any similar agreement in the future. In other words, the relief granted should be adequate to the occasion."

This is exactly ICI's position here. A general injunction prohibiting ICI from imposing restrictions on the resale of bulk drugs covers restrictive agreements "similar" to the one held illegal in the case of griseofulvin, and constitutes relief that is more than "adequate to the occasion."

Similarly, the injunctions which were entered in *United States* v. *Crescent Amusement Co.*, 323 U. S. 173 (1944), which are summarized on page 188 of the opinion, were coextensive with violations which the Court described as follows:

> "The District Court found that each of the seven exhibitors had violated the Sherman Act by
>
> 'A. Creating and maintaining an unreasonable monopoly of the business of operating theatres in the towns of Tennessee, Northern Alabama, and Central and Western Kentucky, in which each has theatres.
>
> 'B. Combining its closed towns with its competitive situations in licensing films for the purpose and with the effect of compelling the major distributors to license films on a non-competitive basis in competitive situations and to discriminate against its independent competitors in licensing films.
>
> 'C. Coercing or attempting to coerce independent operators into selling out to it, or to abandon plans to compete with it by predatory practices.'
>
> The Court found that these violations were offered (a) by combining with each other and with certain major distributors in making franchises, i.e., term contracts for the licensing of films, with the purpose and effect of maintaining their theatre monopolies and preventing independents from competing with them; (b) by combining with each other for the purpose

of dividing the territory in which theatres might be operated by any of them; (c) by combining with each other for the purpose and with the effect of eliminating, suppressing, and preventing independents from competing in the territory in which each operated; and (d) by combining with each other and with certain major distributors in licensing films for the purpose and with the effect of maintaining their theatre monopolies and preventing independents from competing with them" (p. 179).

Another case relied on by plaintiff where the injunctive relief was based on an extensive trial record showing how the enjoined practices had been employed by the defendants to violate the law is *United States* v. *United States Gypsum Co.*, 340 U. S. 76 (1950). The decree provision forbidding standardization of trade practices through concerted agreement (noted on p. 28 of plaintiff's Pre-Hearing Brief) was based on a trial record which was thus summarized in a prior opinion of the Supreme Court:

"Although the license contracts gave the licensor the the right only to fix the minimum price at which the licensee should sell, *United States Gypsum issued a series of bulletins which defined in minute detail both the prices and terms of sale for patented gypsum board. They are printed on nearly a thousand pages of the record.* The bulletins adopted a basing point system of pricing, according to which each licensee was required to quote a price determined by taking the mill price at the nearest basing point and adding the all rail freight from the basing point to the destination. The freight was to be computed on specified uniform billing weights, in order to prevent variations in freight arising from the differences in weight of board made by different manufacturers, and each licensee was directed to charge exactly the same switching, cartage, and extra delivery charges. Specified board sizes and minimum quantities were prescribed, licensees were forbidden to employ commission salesmen without the written consent of the licensor, regulations were prescribed as to the size, quantity and markings of gypsum board used for packing shipments, granting of long-term credit was prohibited, sales on

consignment were enjoined and licensees were forbidden to deliver board directly to a building site.

It is not practicable to quote one of the hundreds of comprehensive bulletins on prices and terms. The industry accepted directions for distribution of product as corollary to price control, so that prices would not be infringed by variations of seller contracts." *United States* v. *U. S. Gypsum Co.*, 333 U. S. 364, 382-3 (1948), underscoring supplied; see also 340 U. S. at 91.

Likewise, in *United States* v. *Loew's, Inc.*, 371 U. S. 38 (1962), plaintiff discusses (at pp. 31-32 of its Brief) the Supreme Court's allowance of a limited prohibition against "temporary refusals to deal." But plaintiff completely ignores the specific factual context giving rise to the injunction. The Supreme Court in this case was dealing with three requests by the government to expand the Final Judgment entered by the Court below. The first of these would have required the defendant film producers to make an initial offer of individual films individually priced, and was justified by the fact that:

"Television stations which asked for the individual prices on some of the better pictures 'couldn't get any sort of a firm kind of an answer,' according to one station official. He stated that they received a 'certain form of equivocation, like the price for the better pictures that we wanted was so high that it wouldn't be worth our while to discuss the matter... the implication being that it wouldn't happen.' A Screen Gems intracompany memorandum about a Baton Rouge station's price request stated that 'I told him that I would be happy to talk to him about it, figuring we could start the old round robin that worked so well in Houston & San Antonio.' Without the proposed amendment to the decree, distributors might surreptitiously violate it by allowing or directing their salesmen to be reluctant to produce the individual price list on request" (*ibid.*, pp. 53-54).

The Government's request for an injunction against "temporary" refusals to deal was similarly motivated. As the Supreme Court said with respect to this request:

"The Government's third request is, like the first,

designed to prevent distributors from subjecting prospective purchasers to a 'run-around' on the purchase of individual films" (*ibid*, p. 55).

In other words, the justification for this injunction was that the record in the case had demonstrated the use of evasive dilatory tactics by the defendants. On the other hand, the record in this case shows nothing but ICI's prompt and total abandonment of the restriction on resale of bulk by ICI, prior to the time of the filing of the government's complaint and immediately upon learning from its U. S. distributor of the Justice Department's investigation (see pp. 5 to 8, above).

E. *Inappropriateness of injunctive relief beyond that decreed in the Schwinn and Bayer-Chemagro cases.*

In the event this Court is of the view that injunctive relief is necessary here, the circumstances of this case do not justify injunctive relief more comprehensive than that decreed in the *Schwinn* case.

In the *Schwinn* case, territorial and customer restrictions were held to have been illegally imposed on 5,000 bicycle dealers and 22 bicycle distributors, and there was no question but that these restrictions were enforced, unlike the situation here. The substantive relief in the District Court's Final Judgment on remand was limited to a simple injunction against the imposition of such territorial and customer restrictions.[22] *A fortiori*, in a case such as this, involving a restraint on alienation which had no market impact, the Court's Final Judgment should, to paraphrase the language of the *Schwinn* case, at the most "enjoin any limitation on the freedom of [purchasers of bulk griseofulvin] to dispose of the [griseofulvin], which they have bought from [the defendants], where and to whomever they

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[22] Sec. V of the *Schwinn* Final Judgment on remand, which is reproduced in its entirety at 291 F. Supp. 564 et seq. (N.D. Ill. E.D. 1968), reads as follows:

"Defendant Schwinn and the Association are each jointly and severally enjoined and restrained from, directly or indirectly, imposing, inducing, or securing any condition or any agreement or understanding that limits the freedom of any distributor or retailer of Schwinn products as to where and to whom it may resell such products, by oral or written statements or by acts of retaliation."

choose" *United States* v. *Arnold Schwinn & Co.*, 338 U. S. 365, 378 (quoted by this Court at 302 F. Supp. 9).

Still assuming *arguendo* that the Court is of the view that injunctive relief is required in this case, such relief should clearly be narrower than that recently awarded in this District in the case of *United States* v. *Farbenfabriken Bayer, A. G. and Chemagro Corp.*, 1969 Trade Cases, para. 72,918. The charges of antitrust violation in the *Bayer-Chemagro* case were far more encompassing than those in the present case. The Government's complaint in Bayer-Chemagro (reproduced and attached hereto as Appendix D) attacks more than one hundred sales and patent license agreements containing not only bulk sale restriction, but other restrictions requiring the licensees to operate in specific fields of business, i.e., so-called "field of use" restrictions.

For the convenience of the Court, there is appended hereto a form of Judgment which tracks, where even remotely relevant to this case, the language of the Final Judgment in the *Bayer-Chemagro* case (see Appendix E).[23] This Judgment goes beyond what is involved either in *Schwinn* or in this case, in that if applied in this case, it would debar ICI from prohibiting its purchasers from reselling drug products "for any consumer end use" or "in any formulation or concentration." Appendix E covers not only the griseofulvin involved in this case, but all pharmaceutical products. Following the lead of the *Bayer-Chemagro* judgment, Appendix E is limited to a term of years.[24]

In both the *Schwinn* and *Bayer-Chemagro* judgments, there are two provisions that should allay the (to ICI com-

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[23] Section IV(E) of the *Bayer-Chemagro* Judgment has been deleted from the form of judgment contained in Appendix E, on the basis that it is surplussage. In a judgment comprehensively prohibiting restrictions on the resale of a drug, there is no need to stipulate that the defendants are free to comply with governmental agency requirements, or to refuse to sell drug products to purchasers whose manner of handling or marketing the products would endanger the health or safety of human beings, or to insert in trademark licenses provisions appropriate to the legal exercise of trademark rights.

[24] The limited term is justified by the limited nature of the violation and the lack of any need for an injunction, see pp. 1 to 10, above. See, in this general connection, *United States* v. *American Angus Association*, 1970 Trade Cases para. 73,268, filed July 13, 1970, where the Justice Department agreed to a final Judgment to be effective for a term of eight years.

pletely unfounded) concern of plaintiff that the defendants in this case will engage in alternative means of achieving forbidden ends. The first of these provisions is a visitation clause, permitting the plaintiff to examine files, interview company officials and request reports on matters relating to the Final Judgment. The second is a retention of jurisdiction clause, permitting the parties "to apply to the Court at any time for such further orders and directions as may be necessary or appropriate for construction, carrying out, modification, termination or enforcement of or compliance with the provisions of this Final Judgment and for the punishment of violations hereof." Assuming that some form of substantive injunction against the bulk resale restriction is found necessary in this case, ICI would not object to a Final Judgment containing these two provisions.

CONCLUSION

The bulk resale restriction in this case was completely inoperative even prior to its effective cancellation three years ago and has had no effect on the U. S. griseofulvin market. ICI has kept a completely hands-off policy as far as the U. S. market has been concerned and has granted five licenses under its dosage patent, and there is no real threat that it will in the future impose or enforce such a restriction. On such a record, no injunction of any kind should issue against ICI. See pp. 1 to 10, above.

Should the Court, contrary to the above position decide that an injunction directed against the bulk resale restriction is necessary and justified, that injunction should not extend to non-drug products or to "manufacturing" licenses under a patent, which involve no restraint on alienation (see pp. 30 to 38, above) and should in no event be more comprehensive than the injunctive relief awarded in the *Schwinn* or *Bayer-Chemagro* cases (see pp. 38 to 41, above, and Appendix C hereto).

Neither the legal decisions cited by plaintiff nor plaintiff's conclusionary, speculative and unsubstantiated industry affidavits supply any justification for compulsory sale relief against ICI (see pp. 11 to 24, above) or for any patent or know-how licensing relief (pp. 25 to 30, above). The affidavits are not only characterized by fallacious and non-probative statistics, but demonstrate the inappropriateness of injecting the Court into the non-judicial arena

of price and margin-fixing activity, as requested by plaintiff.

Respectfully submitted

/s/ Sigmund Timberg
SIGMUND TIMBERG
Attorney for defendant
Imperial Chemical Industries Limited
815 15th Street N. W.
Washington, D. C. 20005

Date: December 3, 1970

AFFIDAVIT OF THOMAS MEREDITH BLAND, DATED NOVEMBER 25, 1970

[Caption Omitted]

I, THOMAS WALTER MEREDITH BLAND, being duly sworn, depose and state that:—

(1) I am, and for the past twenty-four years have been, the Secretary of the Pharmaceuticals Divisions of Imperial Chemical Industries Limited (hereinafter referred to as "ICI") the offices of which Division are located in Macclesfield, Cheshire, England. I am familiar with the course of the present litigation, and have read plaintiff's Pre-Hearing Brief concerning its proposed Final Judgment and the accompanying affidavits. I am executing this affidavit for the purpose of clarifying certain business facts relevant to said papers.

(2) American Home Products Corporation (referred to in plaintiff's papers and in this affidavit as "Ayerst") pursuant to a general agreement dated September 12, 1958, and various supplemental product distribution agreements, operates as ICI's exclusive distributor, importer, and processor of pharmaceutical products in the United States. In my sworn answer to plaintiff's Interrogatory No. 74, filed September 1968, I set forth ICI's relationship to Ayerst as follows:—

> "Imperial has no selling organization in the United States for the marketing of pharmaceutical products and has, for many years, been bound by contract with American, whereby American acts as the exclusive distributor within the United States of pharmaceutical products developed by Imperial. The fact that American is Imperial's exclusive distributor necessarily means that Imperial cannot sell Bulk Form Griseofulvin to Johnson, Schering or any other U.S. firm."

(3) ICI chose to operate in the United States through an exclusive distributor because it did not have, and could not establish in the United States an organisation capable of properly developing and expanding the market for its drugs and of distributing them to all types of users on a nationwide basis. ICI's commercial interests lie in having the U.S.

market developed for its drugs as soon as they reach the appropriate commercial stage and it therefore could not wait the many years it would have taken to develop an adequate promotional and distribution organisation, with its large demand for qualified and knowledgeable medical and sales staff. Moreover, the development of such an organization is a financially prohibitive matter, particularly when one considers the limited number of ICI pharmaceutical products suitable to the U.S. market. ICI has therefore felt that its best interests would be served, and maximum penetration of its products into the U.S. market achieved, by an independent distribution organization, such as Ayerst, already well staffed and oriented to the nature and specific demands of the U.S. market and obligated to devote its best efforts to promoting the marketing of ICI's pharmaceutical products.

(4) ICI's production of griseofulvin, from which it must satisfy United Kingdom's domestic needs and export commitments to the United States and over 100 other countries, is undertaken in limited facilities located in the United Kingdom. For this and other reasons, ICI periodically has encountered difficulties in meeting its world-wide commitments for the supply of both regular and microsize griseofulvin.

(5) ICI exports no microsize bulk griseofulvin into the United States. It exports only the regular form of bulk griseofulvin, which Ayerst subsequently arranges to have processed into the microsize form.

(6) The microsize griseofulvin produced by ICI in the United Kingdom involves the use of a different process from that employed by Ayerst in the United States, is of a different grade and quality from that sold in the United States and is not of a kind that has received new drug approval (NDA) from the U.S. Food and Drug Administration. ICI has not applied for, or received, any NDA's on either regular or microsize griseofulvin.

(7) ICI's terms of trade with respect to griseofulvin and the other drugs exported by it to the United States are that ICI exports the bulk drug f.o.b. U.K. port to Ayerst, so that title to the drug passes to Ayerst and all shipment risks fall on Ayerst once the shipment leaves the U.K. port. Once the drug leaves the U.K. port, ICI has no further involvement with the drug or its marketing in the

United States, other than the provision of such export technical advice as it may be called on to provide as the originator of a drug.

(8) On November 26, 1968, I executed an affidavit in this case in which I set forth the estimated amounts of griseofulvin business done in the United States by Ayerst and its two competitors for the years 1965 to 1967, inclusive, from which it appeared that Ayerst sold far less than either of its competitors and that the market shares of the three competitors varied considerably. There is attached to the present affidavit copies of the two tabulations appended to my 1968 affidavit as Appendix A ("Estimated Shares of Griseofulvin Market (excluding Sales to U.S. Government) 1965-1967") and Appendix B ("Estimated Shares (Dollar Amount) of Total Griseofulvin Market in 1967"). Information as to Ayerst's total sales (including Government sales) for the three-year period 1965-1967 was supplied by me in my answer to Government Interrogatory No. 42(c). The data supplied by Glaxo in response to the same Interrogatory cannot be compared with ICI's figures, because it includes foreign as well as domestic sales by Johnson & Johnson and Schering and involves fiscal year, rather than calendar year, totals.

(9) In my answer to Government Interrogatory No. 43, requesting ICI's and Glaxo's selling prices for bulk griseofulvin, I stated:—

> "Imperial's U.S. selling price for Bulk Form Regular Size Griseofulvin for the years 1965 and 1966 was $78.40 per kilo f.o.b. U.K. In 1967, the selling price for Bulk Form Regular Size Griseofulvin, of somewhat coarser grade than had been supplied in the years preceding, was $77.95 per kilo f.o.b. U.K. In addition, special prices have been quoted to enable American to bid on Government contracts, involving maximum credits ranging from $31.52 per kilo to $32.95 per kilo. Imperial does not know Glaxo's selling prices."

(10) In Glaxo's answer to the same interrogatory, it stated, with reference to its own selling prices:—

> "*Note:* This interrogatory has been modified by stipulation to refer only to sales made to United States Companies or otherwise known to be destined for sale in the United States.

(i) $60.20 per kilo on regular sales; $48.16 per kilo on material used in fulfilling U.S. Government contracts."

(11) In Paragraph 7 of my affidavit of November 6, 1968, I stated that, in cancelling the bulk sale restriction from all its drug distributorship agreements with Ayerst, "Imperial intended unequivocally to eliminate any restriction on the freedom of American to make sales in bulk." In Paragraph 8 of the same affidavit and in my sworn answer to Interrogatory 55(a), I stated it to be ICI's policy "not in any way to influence or restrict American's freedom to make such (bulk) sales." I confirm this to be the continuing policy of ICI.

(12) To my affidavit of November 6, 1968, I attached a lengthy appendix containing all documents in the files of ICI, from the time of the cancellation of the so-called bulk sale restriction in October 1967 to the time of execution of that affidavit, which relate to expressions of interest, inquiries or requests for bulk sales of griseofulvin received by ICI. I stated in paragraph 11 of that affidavit that I had found no document "which in any way indicates a purpose on the part of ICI to influence or restrict (Ayerst's) freedom to resell bulk form griseofulvin supplied to it by ICI, or that the effect of the cancellation has been otherwise than to eliminate any restriction on the freedom of (Ayerst) to resell such bulk form griseofulvin."

(13) I have reviewed ICI's files from November 6, 1968, to the date of execution of this Affidavit and can find no documents indicating any purpose on the part of ICI to influence or restrict Ayerst's freedom to resell bulk form griseofulvin. I can also say that it continues to be ICI's business policy to fulfill orders from Ayerst for bulk griseofulvin according to the capacity of its U.K. plants and without regard to the subsequent resale of the griseofulvin by Ayerst.

(14) Up to the time of its cancellation of the bulk sale restriction, ICI had received no approaches from any U.S. company for supplies of bulk form griseofulvin for the commercial U.S. griseofulvin market. As indicated in my affidavit of November 29, 1968, of eight requests for bulk form griseofulvin received from U.S. sources by ICI, five were for sales to take place in South America, Japan, and countries other than the United States, one was for research

purposes only, and one was for topical use and not the commercial oral use market. With respect to the eighth approach, that of Allergan Pharmaceuticals, I stated that:—

> "It eventually transpired in the course of depositions taken from Allergan employees that the inquiries were being made by a junior employee of that Company on his own and that Allergan had no interest in purchasing Bulk Griseofulvin or entering the dosage form Griseofulvin market."

(15) By way of further implementing ICI's "hands off policy" as far as the United States market is concerned, ICI subsequently decided to make available its dosage patent for non-exclusive licensing on reasonable terms and conditions, and gave notice of said availability in the *Official Gazette* of the Patent Office. This decision and notification are set forth in the Kokulis affidavit of November 7, 1968.

(16) Subsequently, pursuant to the above offer, ICI has granted licenses under its dosage patent, at a royalty rate of 5% of sales value, to five U.S. companies:—Owen Laboratories, Inc., Zenith Laboratories, Inc., West-Ward, Inc., Cole Pharmacal Company and Chromalloy-American Corporation. At no point in any of the negotiations in connection with the issuance of such licenses has any licensee suggested that the royalty rate was unreasonable.

(17) Where ICI's licensee obtains its supplies of griseofulvin from Ayerst, Ayerst pays the royalty to ICI and the licensee is not obligated to pay any royalty. It is only where the licensee obtains its supplies from sources other than Ayerst, which it is free to do under the licence agreement, that the licensee would incur a royalty obligation to ICI. ICI's profits from its sales of bulk griseofulvin (and other drugs) are far larger than the royalty revenues it obtains from licensing its patents on such drugs.

(18) The plaintiff's Pre-Hearing Brief, in footnote 4 of page 5 and in the last sentence of footnote 7 on page 7, indicates that ICI "were willing to accept the bulk sales restriction to be imposed on Ayerst, because Glaxo are imposing a similar obligation on all their licensees." As the writer of the statement (GX-11C) upon which the Government's assertion is based, I feel compelled to say

that this misinterprets what I wrote. ICI was indeed willing to accept the bulk sales restriction, but on the basis that, as indicated in paragraph 2 of my affidavit of November 6, 1968 (as well as in paragraphs 4 and 5 of the affidavit of Mr. Hoare, the Chairman of ICI's Pharmaceuticals Division, dated May 16, 1968), such provisions were in accord with ICI's routine practice throughout the world. I noted, for the benefit of my solicitor, Mr. Methven, that Glaxo had a similar practice but, as indicated, this provision would have been in the Ayerst griseofulvin distribution agreement regardless of Glaxo's practice.

(19) Section I(C) of plaintiff's proposed judgment defines "drug" in the following terms:—

"(C) "Drug" shall be defined as it is in 21 U.S.C. 321 (g)(i); and such term shall also include any form of such drug (bulk, dosage form or otherwise), any intermediate therefor, and any product for which such drug is an intermediate;"

The underscored language has the effect, perhaps unintended, of extending the definition of "drug" to include products which are not in the pharmaceutical field at all but are in the category of dyestuffs, insecticides, plastics, explosives, etc. To illustrate the wide and unreasonable scope of this definition, there is attached hereto a schedule (A) of intermediates for drugs that are also used for other (non-drug) purposes, and (B) of drugs that are themselves used as intermediates for other (non-drug) purposes, respectively.

AFFIDAVIT OF MAURICE E. SILVERSTEIN, DATED OCT. 30, 1970

[Caption Omitted]

MAURICE E. SILVERSTEIN, being duly sworn, deposes and says:

1. I am Vice President of Ayerst Laboratories Division of American Home Products Corporation. I have been associated with Ayerst in an executive or legal capacity for the past six years and am familiar generally with the conditions under which its products, including the antibiotic griseofulvin, are manufactured and sold and with the facts hereinafter set forth in this affidavit. I make this affidavit at the request of Sigmund Timberg, Esq., counsel for

Imperial Chemical Industries (ICI), one of the defendants in the above named action.

2. Ayerst is and at all times has been engaged in the business of making and distributing pharmaceutical products to the medical and pharmaceutical professions in final dosage form for administering to patients on a physician's prescription. In accordance with this practice Ayerst has for more than eight years imported regular size bulk griseofulvin from ICI in accordance with its distribution agreement with ICI of October 4, 1962 and has processed and sold it in finished dosage packages of regular size griseofulvin tablets under the Ayerst label and microsize griseofulvin capsules and tablets under the trademark "GRISACTIN".

3. In October of 1967 Ayerst and ICI by mutual agreement deleted from their distribution agreement a clause which had provided that ICI's consent should be obtained before Ayerst resold any of the bulk griseofulvin supplied by ICI. To the best of my knowledge, information and belief and based upon all available company records Ayerst had at no time prior to the deletion of this clause in 1967 even received any inquiries or requests from any company for commercial supplies of bulk griseofulvin for use in the United States. Ayerst had no occasion to consider making such a sale nor to ask ICI for consent to such a sale.

4. After 1967 and, especially, following publication by ICI of a general offer to grant licenses under its U. S. patent relating to griseofulvin, Ayerst began to receive a number of inquiries from drug companies indicating an interest in griseofulvin and decided that, consistent with its own supply requirements, it would accept orders for griseofulvin from other U. S. drug companies on uniform terms for processing or private label sale. Orders were received by Ayerst on March 10, 1969 from Owen Laboratories for bulk quantities of 1,000,000 capsules of 250 mg. microsize griseofulvin capsules in colors specified by the buyer at a price of $46.30 per 1,000, and on June 24, 1969 from Zenith Laboratories for 500,000 capsules for its use on the same terms and conditions. These orders were accepted and filled by Ayerst and have recently been followed by a repeat order for another 500,000 capsules at the same prices from Zenith Laboratories received by Ayerst on October 9, 1970.

5. In addition to the sales mentioned above Ayerst has offered to supply 250 mg. microsize capsules at the same price of $46.30 per 1,000 to other companies, including Biocraft Laboratories and Dooner Laboratories, and has offered, in addition, to supply capsules of 125 mg. potency at a price of $25.15 per 1,000. Prospective customers interested in the possibility of doing their own processing have been offered the opportunity to purchase bulk regular size griseofulvin at a price of $117 per kg. in quantities of 250 kg. and at a slightly higher price for smaller quantities. During the past three years price quotations on these terms have been extended by Ayerst in response to some 15 different inquiries.

6. Beginning early in 1970 Ayerst also offered prospective purchasers the additional alternative of obtaining supplies of bulk griseofulvin already processed by Ayerst to microsize but not in capsule form, at a price of $135 per kg. in quantities of 250 kg. Since the beginning of 1970 some seven or eight quotations for bulk microsize griseofulvin have been made in response to inquiries for such material and Ayerst has agreed to supply experimental quantities of such material for testing to two companies indicating a possible interest in its purchase.

7. In all of these cases in which sales were made or prices quoted by Ayerst, the quoted price included all royalties payable to ICI for the use of its patent. These royalties are absorbed by Ayerst and the purchasers are not required to make further payments to ICI. The griseofulvin supplied by Ayerst is certified by the U. S. Food and Drug Administration (FDA) and each purchaser, in support of its own application for the necessary approval required by the FDA is given the right to refer to the clinical and manufacturing data previously submitted by Ayerst to the FDA to establish the efficacy and safety of griseofulvin manufactured and supplied by Ayerst. Where Ayerst supplies the product in finished capsules, virtually all of the FDA requirements are already met and it is normally a simple matter for the buyer to obtain Government approval for repackaging and sale under its own label. Where a buyer does his own processing into dosage forms, the FDA requires that he submit technical data substantiating the safety and efficacy involved in the processing which he performs. The additional time and expense in securing such FDA approval is one factor which may lead a pro-

spective buyer to prefer not to purchase in bulk form when he can obtain immediate supplies from Ayerst in an approved dosage form.

8. In recent years no new medical uses for griseofulvin have been discovered and the total U.S. market for griseofulvin products has been relatively static or declining. For each of the years 1967 through 1969 the estimated total U.S. dollar sales of griseofulvin of all manufacturers made to drugstores and hospitals in the U.S. (including Federal Government contracts and the amount of such sales of Ayerst's griseofulvin and its share of this total market were approximately as follows:

	1967	1968	1969
Estimated Total Market	$7,985,000	$7,081,000	$6,712,000
Ayerst Sales	1,318,000	1,134,000	1,596,000
Ayerst Market Share	16.5%	16.0%	23.7%

The foregoing estimates of the total U.S. griseofulvin market have been furnished by the Market Research Department of Ayerst based upon information supplied by an independent market survey organization.

9. The processing and distribution of griseofulvin purchased by Ayerst from ICI in England in coarse particle form involves a substantial number of operations and expenses which must be recovered by Ayerst when it sells this product on the U.S. market. Thus, the original material must be imported and cleared through customs, freight costs and insurance paid, and it must be assayed upon delivery at Ayerst's plant. If microsize griseofulvin is desired, further milling operations are performed to produce particles of the required size and surface area. Additional testing and processing is conducted to convert the material to dosage form as tablets or capsules which are then packaged and labeled in accordance with FDA requirements, and stored in the company's warehouse for shipment to physicians, hospitals and the pharmaceutical trade on orders obtained through efforts of the company's extensive sales and medical detailing staff. At each production stage appropriate quality control tests are conducted and procedures are carried out to obtain the necessary batch certification in conformity with the FDA antibiotic regulations.

10. In addition to the specific activities referred to above, Ayerst maintains a continuing investment in research and development and testing facilities and a staff of some 400 scientists and technicians engaged in research and quality control and to conduct and supervise the toxicological and clinical testing of new or improved drugs and preparation of data required for FDA approval of new drug products, including griseofulvin, together with a staff of approximately 450 medical detail men who are trained to provide educational and current medical and technical information on new drugs to the medical profession in order that these products and their medical indications and side effects may become known to the profession and a demand created for their prescription and sale in the U.S. The substantial investments and expenses which are made by Ayerst and other similar companies in performing these vitally important and necessary functions in the distribution of drugs are not borne to any significant extent by generic or mail order drug houses. These latter companies normally confine their efforts to processing and sale of drugs already well established on the market through the research and technical efforts undertaken by other companies and for which demand has been created in the medical profession by the educational efforts of the marketing and detailing staffs of other companies.

11. The prices which have been quoted by Ayerst for griseofulvin necessarily give recognition to the processing, testing and other expenses incurred by Ayerst as well as the necessity of obtaining a return upon the investment in scientific and marketing facilities and personnel undertaken by Ayerst as one of the companies responsible for the original introduction and acceptance of griseofulvin on the U.S. market.

BRIEF OF DEFENDANT GLAXO CONCERNING FINAL JUDGMENTS PROPOSED BY THE PARTIES, DATED DEC. 3, 1970

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, PLAINTIFF, v. GLAXO GROUP LIMITED and IMPERIAL CHEMICAL INDUSTRIES LIMITED, DEFENDANTS.	Civil Action No. 558-68

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, PLAINTIFF, v. GLAXO GROUP LIMITED and IMPERIAL CHEMICAL INDUSTRIES LIMITED, DEFENDANTS.	Civil Action No. 558-68

BRIEF OF DEFENDANT GLAXO CONCERNING FINAL JUDGMENTS PROPOSED BY THE PARTIES

Introduction

This is an antitrust case, brought by plaintiff to contest the lawfulness of provisions included in certain agreements relating to an antibiotic known as griseofulvin. As originally brought, the case appeared to seek an adjudication on a novel question of law, *viz.*, the validity of a provision in a drug patent license restricting the right of the licensee-manufacturer to sell the product of his manufacture in "bulk" as opposed to finished form. (Complaint, para. 23) As ultimately submitted by plaintiff, however, the case presented only a far narrower and more conventional issue, the validity of contractual provisions restricting the *purchasers* of a bulk commodity (here griseofulvin) from reselling the commodity in bulk form.

The contractual provisions here in question were unequivocally cancelled and abandoned by defendants more than two and one-half years ago. Thereafter this Court held that those cancelled resale provisions had been in violation of Section 1 of the Sherman Act as unlawful restraints on alienation. (302 F. Supp. 1; 163 U.S.P.Q. 668)[1]

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[1] The Court also has held that a provision in a contract between defendants whereby one defendant had agreed to impose such a resale provision on its U.S. vendee was unlawful for the same reason. (1970 Trade Cases, ¶ 73,139) Plaintiff is incorrect in stating that the Court held that "defendants en-

Plaintiff now seeks to employ these narrow and long-since abandoned contractual provisions to justify a broad, elaborate and onerous aggregation of mandatory as well as prohibitory injunctive provisions. It has proposed the entry of a final judgment that would include, *inter alia*, compulsory sales of bulk griseofulvin, compulsory licensing of patents relating to the manufacture and use of griseofulvin, compulsory disclosure of extensive technical data, and various restrictions, going far beyond any adjudication in this case, upon licensing agreements entered by defendants with regard to not only griseofulvin but all drugs and drug products that are subject to United States patents. We will show that the circumstances of this case are such that no injunction at all is necessary. In case the Court should conclude otherwise, however, we have proposed for the Court's consideration a final judgment that unlike the one proposed by plaintiff bears a reasonable relationship to the issues actually presented in this litigation. Our proposed judgment would fully and effectively forbid any revival of the practices that have been declared impermissible—and would forbid such a revival not only as to griseofulvin but as to a wide range of other products as well. For reasons described below, we urge that the form of final judgment proposed by plaintiff is plainly inappropriate in the circumstances of this case, and that if any injunctive relief is given it should be in the form proposed by us.

I. STATEMENT OF THE ISSUES

The issues may be fully understood only after a more precise statement of the case than plaintiff has offered.

Defendants Glaxo Group Limited ("Glaxo") and Imperial Chemical Industries Limited ("ICI") are English corporations. Each maintains its principal place of business in London. Neither is alleged to have conducted business in the United States. (302 F. Supp. 1, 3, 4) Glaxo entered separate agreements in 1959 with Schering Cor-

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gaged in per se violations of the anti-trust laws, by preventing bulk sale of the antibiotic drug griseofulvin." (Plaintiff's Brief (hereafter "PB"), p. 1). The decisions of the Court referred to in the text and in this note were directed only to restrictions on the bulk *resale* of griseofulvin purchased from defendants, a very different issue. Compare *United States* v. *Arnold, Schwinn & Co.*, 388 U.S. 365 (1967), with *General Talking Pictures Corp.* v. *Western Electric Co.*, 305 U.S. 124 (1938).

poration ("Schering") and Johnson and Johnson, Inc. ("Johnson"), by the terms of which Glaxo agreed, *inter alia*, to sell to them griseofulvin in bulk form. The vendees were each given non-exclusive rights to prepare and market griseofulvin in dosage form, but they were forbidden, without Glaxo's consent in writing, to resell griseofulvin in bulk form to independent third parties. (Complaint, ¶ 23, Glaxo Answer, ¶ 23) ICI concluded a somewhat similar agreement with its exclusive American distributor, American Home Products Corporation ("AMHO"), in 1962. (Complaint, ¶ 24, ICI Answer, ¶ 24)[2] At the time Glaxo entered its agreements, it was unaware that the resale provisions were, or might subsequently be thought to be, in violation of American law. (Affidavit of Herbert William Palmer, Attachment A hereto (hereafter "Palmer Affidavit"))

Very shortly after the institution of this suit, when Glaxo realized that the provisions raised a legal question, they were unconditionally deleted and abandoned. This was done in letters written to Schering on April 23, 1968, and to Johnson on April 29, 1968. (Palmer Affidavit) It is these specific resale provisions alone, and not the agreements in which they were formerly included, that were subsequently found by the Court to be in violation of the Sherman Act.[3]

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[2] A 1960 agreement between Glaxo and ICI relating to griseofulvin had provided that ICI would "use its best endeavors to prevent" its vendees from selling in bulk. Plaintiff claims that "ICI acceded to this clause [which has also been declared unlawful by the Court (see p. 1, n. 1, *supra*)] on the basis that Glaxo was to impose the same restriction upon its licensees" (PB, p. 5, n. 4), and was "willing to accept the bulk sales restriction to be imposed on Ayerst, because Glaxo 'are imposing a similar obligation on all their licensees'." (PB, p. 7, n. 7) This attempt to show "that the bulk sale restriction on each licensee was the *quid pro quo* for the others" (*Ibid.*) misstates the documentary evidence. ICI never suggested that it intended to impose a bulk restriction on AMHO only "on the basis" that, or "because," Glaxo's licensees were so restricted. The fact is that the bulk restriction imposed by ICI on AMHO was a reflection of ICI's standard policies in its drug agreements with AMHO at the time, and was not a "*quid pro quo*" for anything.

[3] For this reason plaintiff's memorandum is simply incorrect in describing generally the license agreements between Glaxo and Schering and Johnson, and then stating that "These are the agreements held to be per se in unreasonable restraint of trade, by this Court's Order of November 20, 1968," (PB, p. 4) and equally incorrect in describing the ICI agreement with Ayerst and then stating that "The foregoing 1962 agreement is that held to be

Nothing in the record of these proceedings supports any suggestion that defendants have subsequently sought, in any fashion or under any guise, to restrict or discourage the resale by their vendees of griseofulvin in bulk form. On the contrary, the record includes sworn statements that no such efforts have been made. Johnson and Schering have each stated unequivocally that their current policies with regard to the manner and form of their sales of griseofulvin are entirely the consequences of their independent commercial decisions, and Glaxo has similarly sworn that it has not sought, by discussion, agreement or other means, to influence or control these judgments. (Palmer Affidavit; Affidavit of John H. Kip, Attachment B hereto (hereafter "Kip Affidavit"); Affidavit of Richard J. Bennett, Attachment C hereto (hereafter "Bennett Affidavit"))

The absence of such efforts is confirmed by the disparity of the three vendees' present policies: AMHO has elected to offer to sell griseofulvin in bulk to third parties; Schering and Johnson, which customarily have not sold drugs of any kind in bulk in the United States, have thus far each chosen not to adopt a policy with regard to griseofulvin different from that which they have each independently followed with respect to other drugs, although each is entirely free to change its policy if and when it wishes to do so. (Kip Affidavit; Bennett Affidavit) The short of the matter is that there now exists a market of precisely the kind sought by the antitrust laws, in which each of the firms involved determines independently in what manner and form it will sell griseofulvin.

Plaintiff evidently prefers to obscure these simple facts. It returns time and again to the unfounded postulate of an existing conspiracy, as to which it never sought an adjudication or offered the slightest evidence, by which defendants and their vendees allegedly continue to restrict the sale of griseofulvin by the latter.[4] It repeatedly in-

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per se in unreasonable restraint of trade by this Court's Order of June 4, 1969," (PB, p. 5) and in asserting that "the original pooling agreement between Glaxo and ICI" was "held to be in unlawful restraint of trade" (PB, p. 22).

[4] Plaintiff's original complaint did not charge any conspiracy between defendants and their vendees going beyond the challenged contractual provisions themselves, and it is significant that when plaintiff sought to amend its complaint on September 23, 1968, well after the contractual provisions later

timates that this Court has condemned more than the abandoned resale provisions, despite the plainly contrary terms of its orders. It continues to charge, despite the Court's express refusal to permit amendment of the complaint to introduce such a charge into the case, that there has existed a conspiracy among Glaxo, Johnson and Schering, whereby Glaxo would refuse to deal in griseofulvin with other firms in the United States.[5] Each of these techniques reflects plaintiff's persistent efforts to escape the specific and precisely directed terms of the Court's orders, and to draw into the case much wider issues. The truth is that this litigation involves nothing more complex than restraints upon alienation that were finally and unconditionally abandoned long before they were condemned by this Court.[6] It is as to those long past violations, and nothing more, that any consideration of relief should be directed.

The purpose of the antitrust laws is to strike down restraints that inhibit or prevent the operation of a free market. In a free market, persons may dispose of products purchased by them in such manner as they see fit. By the

adjudged to be unlawful had been cancelled, it did not seek to charge a conspiracy restricting the sale of bulk griseofulvin by defendants' vendees. Similarly, when plaintiff subsequently defended against ICI's motion for judgment on the ground of mootness, it made no claim of a continuing conspiracy, although such a claim would in itself have been sufficient to defeat ICI's motion. On the contrary, even after that date plaintiff was continuing to assert that defendants' unlawful conduct had consisted simply of "preventing [their vendees] from selling to smaller companies" by "restricting their patent licenses * * *." See Objections of Plaintiff to November 6, 1968, Recommendations of Pretrial Examiner (Nov. 13, 1968), p. 2.

[5] See, *e.g.*, PB, p. 2 and note 2. Plaintiff's references to this charge are plainly improper in light of this Court's prior ruling that "the proposed charges are not directly related, in a legal sense, to those near disposition in the original case," and that for this and other reasons plaintiff would not be permitted to try them in this litigation. (302 F. Supp. at p. 16) The Court can hardly be expected to undertake to pass on the validity of this charge after having formally excluded it from the case. Similarly, plaintiff's repeated complaint that defendants have declined to sell griseofulvin, and that Glaxo has refused to license its patent covering the manufacture of bulk griseofulvin, ignores the fact that the only issue tried in this case involved restraints on defendant's *vendees*, not any alleged restraints on defendants' choice of vendees or licensees.

[6] As this Court noted in its prior opinion herein, in this case "griseofulvin has been treated as though it were an unpatented product" and "the case has not been characterized as a patent misuse, patent licensing, or know how licensing problem." (302 F. Supp. at p. 9, n. 40)

same token, however, persons may, absent illegal monopoly or conspiracy, decline to deal with other persons if they see fit in the exercise of their individual business judgment to do so. It is evident that what plaintiff actually seeks in this case is not the creation of a free market by the elimination of unlawful restraints, but rather creation of a controlled market whereby there is imposed on defendants the forced status of a public utility and the distribution of griseofulvin is dictated by judicial decree rather than by the free interplay of market forces. It can only be on this basis that plaintiff repeatedly relies on the charge that defendants and their vendees have to date each either declined to sell bulk griseofulvin to others or offered to sell it at prices that plaintiff finds unsatisfactory, and complains that "bulk griseofulvin is [allegedly] kept out of the hands" of "generic drug houses" and "private label houses" (PB, p. 10), that such elements therefore "will remain frozen out of the market" and that "the effect is that the public is denied the benefit of the independents' and generic sellers' competition, in the form of price * * * and otherwise" (PB, p. 11).

Contrary to plaintiff's apparent suggestion, nothing in the antitrust laws guarantees "generic drug houses" and "private label houses" access to the griseofulvin market on their own terms. Like other would-be purchasers, such companies are entitled to have their possible vendors free from unlawful constraint in considering their offers to buy, and to no more or less. By reason of the eradication that has already taken place of the contractual provisions which this Court has found to be offensive these companies are already in this position as to griseofulvin. And upon entry of the judgment proposed by Glaxo, they will be secured in this position by the contempt powers of the Court. At this point the antitrust function is plainly exhausted. If they are thereafter unable to purchase griseofulvin at prices satisfactory to themselves, it is because of the independent business judgment of their potential vendors and the working of market forces which it is the function of antitrust to preserve not destroy. "It is not for the courts to realign and redirect effective and lawful competition where it already exists and needs only to be released from restraints that violate the antitrust laws." *United States* v. *National Lead Co.*,

332 U.S. 319, 353 (1947). The only "competitive evils condemned in the antitrust adjudication" and "past market effects of the restraint" (PB, p. 12) are dissipated by the very disappearance of the restraining contractual provisions—a disappearance which in itself did "effectively pry open" (PB, p. 2) the market to the interplay of competitive forces.[7]

To the extent that plaintiff makes any attempt to deal with this basic difficulty in its position, it does so by simply assuming that there still exists a conspiracy whereby defendants' vendees are illegally prevented from reselling griseofulvin in bulk form.[8] There has been no adjudication in this case of any such proposition, and it is contrary to all the evidence. (Palmer, Kip and Bennett Affidavits. See also p. 6, n. 4, *supra*)[9] Plaintiff's attempt to prove it consists solely of the *post hoc* approach of elaborate reiteration in a variety of forms of the circumstance that those vendees have not in fact resold griseofulvin in bulk form at prices satisfactory to plaintiff. It need hardly be

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[7] Plaintiff has never presented any persuasive evidence that defendants' vendees would have sold bulk griseofulvin during the period when the bulk restrictions were in effect had it not been for those restrictions, *i.e.*, that those restrictions had an actual effect on the market. The evidence is to the contrary. (Kip Affidavit; Bennett Affidavit) There are still pending before the Court motions of the parties relating to interrogatories by Glaxo attempting to secure from plaintiff a candid admission of its lack of evidence on this subject, an admission that plaintiff has gone to great efforts to avoid making.

[8] "Before and since the filing of this complaint the defendants' vendees have, *pursuant to their unlawful agreements with defendants*, refused to sell the product in bulk to generic drug houses or other independents." (PB, p. 6) (Emphasis added.)

"*As long as griseofulvin has been marketed in the United States*, the defendants have illegally prevented its sale in bulk form." (PB, p. 14) (Emphasis added.)

See also the statement of plaintiff's counsel in argument before this Court on October 5, 1970, that the fact that defendants cancelled the challenged contractual provisions "doesn't mean that they didn't continue their illicit understanding, combination, and conspiracy before, after, and during this entire period," and that one of plaintiff's contentions "is that there is an understanding of both directions, in that Schering and Johnson & Johnson are beneficiaries of the restriction and that they are all in it together and they are all engaged in a combination to restrain trade and have been."

[9] Even if such a conspiracy did exist today, the appropriate method for dealing with it would clearly be to enjoin its continuance, and thereby pry open the market to competitive forces, rather than to impose onerous compulsory sales and compulsory licensing requirements of the kind that plaintiff seeks.

pointed out, however, that this circumstance is in itself entirely neutral and permits no inference of conspiratorial conduct. And with the collapse of its unproved allegation of continuing conspiracy there falls plaintiff's entire case for the extremely broad judgment that it has proposed.

II. APPLICABLE LEGAL PRINCIPLES

In considering the question whether an injunction is appropriate in this case, and if so what its terms should be, it is essential to keep in mind the principles that govern the formulation of injunctive relief in antitrust cases. Those principles are those which traditionally have obtained in courts of equity. *De Beers Consolidated Mines* v. *United States*, 325 U.S. 212, 218-19 (1945); *United States* v. *National City Lines*, 134 F. Supp. 350, 354-55 (N.D. Ill. 1955). Under them, the "sole function of an action for injunction is to forestall future violations." *United States* v. *Oregon State Medical Society*, 343 U.S. 326, 333 (1952). The issuance of an injunction is altogether "unrelated to punishment or reparations" for previous wrongdoing. *Ibid.* See also *Proctor* v. *Bayley*, 42 Ch. D. 390 (1889); *Walling* v. *Youngerman-Reynolds Hardwood Co.*, 325 U.S. 419 (1945). Thus "the statute confers on the Government no absolute right to an injunction upon a showing of past violation of the antitrust laws by defendants." *United States* v. *Borden Co.*, 347 U.S. 514, 519-20 (1954). The fact of a past violation "means nothing except in so far as in some cases it may show a likelihood of recurrence of the unlawful conduct; it does not raise any presumption of a general propensity for wrongdoing." *United States* v. *National City Lines, supra*, at p. 356.

Whatever the record of past violations, an injunction ordinarily does not issue "to prevent a practice which has been definitely and permanently discontinued." *Bowles* v. *Carnegie-Illinois Steel Corp.*, 149 F.2d 545, 547 (7th Cir. 1945). See also *Proctor* v. *Bayley, supra*. There must be "some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive." *United States* v. *W. T. Grant Co.*, 345 U.S. 629, 633 (1953). And the fact that the challenged conduct was not terminated until after the commencement of suit, and that plaintiff has, as here, secured an adjudication of its illegality, is no reason to disregard that termination in determining whether equitable relief is necessary to pre-

vent future violation. *Id.* at pp. 633-34; *Walling* v. *Youngerman-Reynolds Hardwood Co., supra; United States* v. *Parke, Davis & Co.*, 1960 Trade Cases, ¶ 69,776 (D.D.C.), *reversed on other grounds*, 365 U.S. 125 (1961); *United States* v. *National City Lines, supra*, at p. 362.

In this case, the contractual provisions found by the Court to be impermissible were unconditionally abandoned by defendants more than two and one-half years ago. Although plaintiff persists in its allegations of a continuing conspiracy, it has proffered, and the record now contains, not the slightest support for these allegations. To the contrary, the record shows that there now exists what plaintiff professedly is anxious to obtain: a truly free market—one in which defendants and their vendees are neither compelled nor forbidden to sell griseofulvin in bulk form, but rather are free each to decide upon the basis of its separate commercial judgment in what manner and form it will sell griseofulvin. Plaintiff offers no evidence of any likelihood that the past violations will recur. Under these circumstances we submit that this Court should, pursuant to the authorities just discussed, decline to enter *any* injunction despite the adjudication of past illegality.

Even if the Court concludes to enter an injunctive decree, to make assurance doubly sure that the already abandoned practices found to be unlawful are not resuscitated, that decree should be responsive to the issues actually presented by this litigation. There is no warrant or justification on any theory for the elaborate and extreme form of judgment plaintiff has proposed.

The truth is that plaintiff seeks drastically to extend the principles that govern the formulation of antitrust relief. The essential standard has been that the decree should "return the parties as near as possible to the *status quo* existing prior" to the violation. *International Boxing Club* v. *United States*, 358 U.S. 242, 258 (1959). The Supreme Court observed nearly sixty years ago that it is ordinarily sufficient for these purposes to restrain future performance of the acts found to be impermissible. *Standard Oil Co.* v. *United States*, 221 U.S. 1, 77 (1911). The trial court should not, as plaintiff here urges, "range far beyond the hard facts of the question actually tried in the case * * *." *United States* v. *National City Lines, supra* at p. 355. The finding of an antitrust violation does not "invest a court

with a license to embark upon a general program of comprehensive control of the defendants' business." *Ibid.* Injunctive relief should instead be limited "by the circumstances involved in the litigation." *Id.* at p. 359.

III. GLAXO'S PROPOSED JUDGMENT

In the event that the Court concludes that some form of injunctive relief is appropriate, the form of final judgment proposed by Glaxo incorporates a series of provisions that would give full assurance to plaintiff and the Court that the resale provisions found to be unlawful could not be revived. Glaxo's judgment is by no means niggardly in scope, for it applies not only to griseofulvin but to all other drugs as well. Indeed, the relief provisions of Glaxo's proposal are closely modelled on a decree recently entered by this Court in a closely similar case with plaintiff's consent. *United States* v. *Farbenfabriken Bayer A.G.*, 1969 Trade Cases ¶ 72,918 (D.D.C. 1969). Those provisions include the following:

(1) Each defendant would be enjoined from selling griseofulvin *or any other drug* in the United States pursuant to any agreement which prohibits the purchaser from reselling the drug to any person, in any area of the United States, for any consumer end use, in any formulation or concentration, or for use outside the United States.

(2) Each defendant would be enjoined from refusing to sell griseofulvin *or any other drug* in the United States to a purchaser because of the purchaser's refusal to enter an agreement of the kind described;

(3) Each defendant would be enjoined from placing upon packages, or requiring any purchaser to place upon packages, any statement that purports to create an agreement of the kind described;

(4) Each defendant would be enjoined from agreeing with the other defendant or with any third person to engage in the conduct described;

(5) Each defendant would be made subject to disclosure and visitation requirements very similar to those included in plaintiff's proposed final judgment and identical to those in the consent decree in *Bayer, supra.*

The *Bayer* judgment contained provisos to the effect that its provisions should not prohibit the defendants from the following:

(1) Placing names or marks upon any package, licensing names or marks to any person, and, in cases in which such marks or names are employed, from exercising such rights as defendants may have under the law;
(2) refusing to sell drug products to any purchaser whose handling or marketing of the products endangers the health or safety of human beings or plant or animal life;
(3) complying with any requirement imposed by any governmental agency with respect to any drug product.

Glaxo's proposed judgment contains no such provisos, because we regard them as unnecessary to authorize the conduct to which they refer.

We submit that the provisions of Glaxo's proposed form of judgment fully and effectively respond to the statutory violations found in this litigation, and that their propriety as remedial measures in a case of this kind is conclusively demonstrated by plaintiff's acceptance of them in a recent and markedly similar situation.

IV. PLAINTIFF'S PROPOSED JUDGMENT

In sharp contrast to the decree discussed above, plaintiff has proposed the entry of a final judgment that incorporates each of the following ingredients:

(1) a prohibition of agreements under which defendants seek to restrict any person in the manner or form in which it resells drugs purchased for use in the United States;
(2) a requirement of compulsory sales by defendants of griseofulvin to any and all applicants for ten years, or as long as Glaxo makes or offers to make sales of griseofulvin in the United States, whichever period proves shorter;
(3) compulsory licensing of defendants' patents relating to the manufacture and use of griseofulvin, including any patents issued within the five years following the entry of judgment;

(4) broad disclosure of technical data, either now existing or developed within the five years following the entry of judgment, which relate to the manufacture, processing or use of griseofulvin;
(5) various restrictions upon licensing agreements entered by defendants with regard, not merely to griseofulvin, but to all drugs and drug products that are subject to United States patents; and
(6) visitation and disclosure requirements, including defendants' obligation upon court order to bring to the United States their documents and records, officers and employees.

We comment specifically below on each of these ingredients of plaintiff's proposal.

A. Prohibition of agreements or understandings under which any party undertakes not to resell, or is restricted in the manner or form in which it resells, drugs which that party has purchased for use in the United States.

These paragraphs of plaintiff's proposed judgment (¶¶ IV A and B) are responsive to the issues presented in this litigation. Accordingly, even though they are not restricted, as they might well be, to the product involved in this case, Glaxo does not object to them in substance, and has included similar provisions in the form of final judgment that it has itself proposed.

B. Compulsory sales of griseofulvin to any and all applicants, for ten years or as long as Glaxo makes or offers to make sales of griseofulvin in the United States, whichever period proves shorter.

The linchpin of plaintiff's argument in support of this provision of its proposed judgment (¶ IV C) is the repeated allegation that defendants and the American firms with which they now deal continue by agreement or understanding to restrict the sale of griseofulvin in bulk form. It is enough to reiterate that plaintiff has proffered not the slightest evidence to support these allegations, and that the record in these proceedings instead contains only uncontradicted evidence that no such combination or conspiracy exists.

To impose a compulsory sale provision here would go far beyond the remedial function of freeing the market from unlawful restraints—it would compel defendants to take affirmative action of a kind that there is no reason even to suspect they would ever have taken had the bulk provisions held illegal in this case never existed.

Plaintiff's demand for compulsory bulk sales by defendants is particularly inapposite in light of the nature of the adjudicated restraint in this case. That restraint was not in whole or in part one on bulk sales by defendants. Rather, it was one on such sales by defendants' vendees. We believe that the record clearly establishes that even had the restraint never existed those vendees, each in the exercise of its own individual and independent business judgment, would not have sold bulk griseofulvin during the time it did exist. (See Kip and Bennett Affidavits) But in any event, the restraint is now lifted and, if the Court sees fit, any conceivable revival of it can be effectively blocked by a decree of the kind proposed by Glaxo, leaving the vendees to act independently as they see fit. To require *defendants* to make bulk sales to others is simply unresponsive to any issue litigated in this case, and is in no way calculated to "dissipate the past market effects" or "the competitive evils" (PB, p. 12) of the only practice found unlawful herein, since any such effects could only have been in terms of forestalling bulk sales not by defendants but by others who are now entirely free to resell.

The anomaly in plaintiff's proposal is further highlighted by the fact that it seeks to give any and all would-be purchasers an absolute right to buy bulk griseofulvin from defendants, so long as defendants sell to their present vendees, at the same price as is paid by those vendees.[10] A moment's reflection demonstrates how far the proposal goes beyond attempting to recreate the market conditions that would have existed but for the bulk restrictions in defendants' contracts with their vendees. As stated above, it was not defendants, but their vendees, to whom the bulk restrictions applied, and hence any compulsory sale requirement imposed on defendants is simply unresponsive to the only adjudication that has been made in this case. Moreover, even if it is assumed, in the teeth of the evidence,

[10] Presumably this is the intent and import of the "non-discrimination" language in Paragraph IV (C) of plaintiff's proposed form of judgment.

that had they not been subject to the restraints, defendants' vendees would have chosen to sell bulk griseofulvin to others, it is an absolute certainty that they would never have done so at a price no higher than that at which they themselves bought. For this reason alone there is no basis for a mandatory injunction of the kind proposed by plaintiff requiring that defendants make griseofulvin generally available at "non-discriminatory prices", *i.e.*, at the prices at which they from time to time sell to their present vendees, for such an injunction on its face goes drastically beyond a return of the parties to the status quo existing apart from the violation.

Plaintiff claims that unless "independent drug companies" are permitted to buy on this basis they "will continue to be kept out of the market." (PB, p. 15) Far from justifying plaintiff's compulsory sale provision, this assertion is actually a clear admission that the bulk restrictions never had actual market effects even when they existed. For it was obviously not the bulk restrictions, but the most elementary economic self-interest, that prevented defendants' vendees from reselling bulk griseofulvin to others at their own purchase price.

Plaintiff's rehearsal of the occasions on which compulsory sales provisions have been included in antitrust relief adds nothing. There have by the same token been many cases involving, as does this case, restraints on alienation in which such provisions have evidently been found unnecessary or inappropriate. See, for example, *United States* v. *Farbenfabriken Bayer A.G.*, 1969 Trade Cases ¶ 72,918 (D.D.C. 1969); *United States* v. *Arnold, Schwinn & Co.*, 1968 Trade Cases, ¶ 72,480 (N.D. Ill. 1968); *United States* v. *Serta Associates, Inc.*, 1968 Trade Cases ¶ 72,583 (N.D. Ill. 1968); *United States* v. *Permatex Co.*, 1966 Trade Cases ¶ 71,754 (E.D.N.Y. 1966).

C. Compulsory licensing of United States patents relating to the manufacture and use of griseofulvin, including any patents issued within the five years following the entry of judgment.

It is important first to mark the terms of plaintiff's argument in support of this provision of its proposed judgment (¶ IV D). Plaintiff envisions compulsory patent licensing as supplemental to its proposed compulsory sales

requirement. It follows that, should the Court decline to impose a sales requirement, there could *a fortiori* be no justification for the imposition of such compulsory licensing, and that would be the end of the matter. On the other hand, even if the Court should impose a compulsory sales requirement, it must nonetheless examine separately the question whether compulsory patent licensing is independently justifiable. We submit that it plainly is not.

Plaintiff offers two explanations for the addition of compulsory licensing to compulsory sales. First, it suggests that such licensing is needed "as a damper upon unreasonable price demand by the defendants." (PB, p. 21) This is patently insubstantial. Even if the Court were to determine that the prices charged by defendants should be regulated by a judgment rather than by the marketplace, with the adoption of plaintiff's compulsory sales provision defendants would be forced to make sales of griseofulvin "on reasonable and non-discriminatory terms and prices * * *." (Plaintiff's Proposed Judgment, ¶ IV D) In these circumstances, there would be no reason to add yet another system of requirements, involving still further limitations upon defendants' lawful activities.

The other and more basic justification articulated by plaintiff for compulsory patent licensing is stated to be "to assure third parties alternative sources of supply should defendant elect no longer to sell in the United States." (PB, p. 18) It is important to observe the purpose for which this requirement would evidently be imposed. Plaintiff does not seek here to "return the parties as near as possible to the *status quo* existing prior" to any violation. *International Boxing Club* v. *United States, supra* at p. 258. It seeks instead to guarantee the continued availability of griseofulvin in the American market. To this end, plaintiff proposes to deny defendants an essential ingredient of their rights under the patent system: it has long been settled to be "of the very essence of the right conferred by the patent, as it is the privilege of any owner of property to use or not to use it, without question of motive." *Continental Paper Bag Co.* v. *Eastern Paper Bag Co.*, 210 U.S. 405, 429 (1908). See also *Leuschner* v. *Kuther*, 314 F.2d 71, 73 (9th Cir. 1963). There is no discernible reason why the fact that defendants were at one time parties to agreements that contained provisions since found to have been unlawful in a particular respect should

be deemed to necessitate such a drastic forfeiture of their rights.[11]

Even if the Court should conclude that, as plaintiff argues, compulsory patent licensing should be decreed to assure third parties alternate sources of supply should defendant elect no longer to sell in the United States, the result should not be a provision of the kind tendered by plaintiff. Rather, plaintiff's own rationale would support no more than a requirement that *if* Glaxo were to withdraw from the sale of griseofulvin in the United States, at such time compulsory patent licensing would come into play.[12]

It adds nothing to plaintiff's case to parade the sundry situations in which patent licensing has been imposed. It suffices that, precisely as there are cases that have included such relief, so there are cases that have terminated without its imposition, and with plaintiff's acquiescence. See, for example, *United States* v. *Farbenfabriken Bayer A.G.*, 1969 Trade Cases ¶ 72,918 (D.D.C. 1969); *United States* v. *Hughes Tool Co.*, 1958 Trade Cases ¶ 69,001 (S.D. N.Y. 1958); *United States* v. *Combustion Engineering, Inc.*, 1957 Trade Cases ¶ 68,852 (S.D.N.Y. 1957); *United States* v. *Ohio Crankshaft Co.*, 1956 Trade Cases ¶ 68,329 (N.D. Ohio 1956). The question is not one of custom or relative frequency, but of appropriateness to the circumstances presented in the particular litigation.

D. Compulsory disclosure of technical data, either now existing or developed within the five years following the entry of final judgment, which relate to the manufacture, processing or usage of griseofulvin.

This provision of plaintiff's proposed judgment (¶¶ IV D,

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[11] It is appropriate here to reiterate this Court's observation that in this case

> "griseofulvin has been treated as though it were an unpatented product * * * the case has not been characterized as a patent misuse, patent licensing, or know how licensing problem." (302 F. Supp. at p. 9, n. 40)

[12] Plaintiff urges that compulsory licensing of Glaxo's microsize griseofulvin patent is a necessary complement to any decree requiring ICI to sell griseofulvin in bulk, so that its vendees may grind the regular size griseofulvin that ICI currently sells into microsize. The short answer to this suggestion is that even if the Court should conclude that any would-be purchaser is to be given the absolute right to buy bulk griseofulvin, no such licensing would be necessary because microsize griseofulvin could be purchased from Glaxo.

V A) is, of course, contingent upon the imposition by the Court of compulsory patent licensing. Should the Court decline to impose licensing requirements, there should be no occasion to consider the necessity for the disclosure of technical data. Even if, however, the Court should order compulsory licensing, it does not by any means follow that plaintiff's unrestricted provision as to technical data should also be adopted by the Court. The Court should proceed with great care in this area, lest it "discourage rather than encourage" research important to the public interest. *United States* v. *National Lead Co.*, 332 U.S. 319, 359 (1947). Any requirement of disclosure of technical information in the circumstances of this case would raise issues of wide significance, which cannot be adequately assessed and explored without an understanding of the particular techniques employed in the manufacture and processing of griseofulvin. Because we think it highly unlikely that the Court will have occasion to reach the question of such disclosure, we do not deal with these matters here. Rather, we respectfully and urgently request that should the Court determine to consider requiring the disclosure of technical information, the Court set that particular matter for a full hearing at which we be given an opportunity to provide an appropriate exegesis of the various problems and possible arrangements.

E. Various restrictions upon licensing agreements entered by defendants with regard, not merely to griseofulvin, but to all drugs and drug products that are subject to United States patents.

Plaintiff asks this Court to enjoin defendants from entering any agreement or understanding with any licensee under any United States patent relating to any drugs or drug products, if that agreement or understanding restricts sales in bulk or otherwise controls any party to the agreement in its selection of the persons with whom it wishes to deal. (Plaintiff's Proposed Judgment, ¶¶ IV G, H) It seeks to support its position by a lengthy exposition of what it characterizes as the "similar agreement" and "prohibition of lawful acts" rules.

We submit that whatever may be the general scope or application of these "rules," a prohibition of the kind postulated would be entirely unwarranted in the particular circumstances of this litigation. Plaintiff's own argument

makes it clear that the prohibition which it seeks is designed to prevent defendants from placing in any manufacturing patent license a provision limiting the method of distribution of the product manufactured under the license. As we have earlier noted, the case originally brought by plaintiff here squarely placed in issue the validity of such limitations, which have in the past been generally deemed to be entirely lawful. *Cf. General Talking Pictures* v. *Western Electric Co.*, 305 U.S. 124 (1938). It was plaintiff itself which chose to remove this issue from the area of controversy by ultimately restricting its contentions in this case to the separate, different and far narrower issue of the validity of restraints upon the resale of a purchased commodity. To permit plaintiff now, under the guise of securing adequate relief, to have an injunction reading on precisely the conduct that it consciously decided not to challenge on the merits would be to permit it to retreat from the battle and yet win the war. If any of the horribles that plaintiff parades in attempting to justify this kind of injunction come about in the future with respect to griseofulvin, it will be time enough then to decide the question whether manufacturing patent license restrictions, as contrasted with restraints on resale, are to be forbidden.

As a separate and distinct matter, it is important to observe that even on plaintiff's own argument there is not the slightest justification for the inclusion in this portion of its proposed judgment not merely of griseofulvin, but of all drugs and drug products that form the subject of any United States patent. The cases cited by plaintiff in this portion of its brief all involve consideration of injunctive provisions relating to the particular products found to have been unlawfully restrained. No case cited by plaintiff provides the slightest support for an injunction prohibiting lawful acts taken with respect to products altogether distinct from any involved in the litigation.[13] Accordingly, even if the Court should elect to impose this additional injunction upon defendants' activities in licensing griseofulvin, despite the fact that plaintiff intentionally chose

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[13] Compare *Hartford-Empire Co. v. United States*, 323 U.S. 386, 423 (1945), where despite the very broad and egregious nature of the adjudicated violations the United States conceded that an injunctive provision could not properly cover all products and should be restricted to glassmaking machinery and glassware.

not to press in this case the question of the validity of defendants' activities in this regard, there can be no conceivable warrant for the inclusion in the injunction of products other than griseofulvin. If plaintiff genuinely fears future violations involving such practices with respect to other drug products, they "should fairly be left to a later action when and if it proves necessary." *United States* v. *National City Lines, supra* at p. 335.

F. Visitation and disclosure requirements.

Defendant Glaxo offers no objection to the general thrust of these provisions in plaintiff's proposed judgment. (¶ VI) Very similar provisions, conforming precisely to the visitation provisions in *Farbenfabriken Bayer, supra,* are included in the form of final judgment proposed by Glaxo.

CONCLUSION

For all the foregoing reasons, the Court should reject plaintiff's proposed form of judgment and enter that proposed by Glaxo.

Respectfully submitted,

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REPLY REHEARING BRIEF OF UNITED STATES CONCERNING FINAL JUDGMENT, FILED DEC. 17, 1970

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, PLAINTIFF, v. GLAXO GROUP LIMITED and IMPERIAL CHEMICAL INDUSTRIES LIMITED, DEFENDANTS.	Civil Action No. 558-68

Introduction

A.

There are three principal disputed aspects of relief in this case; (1) whether griseofulvin should be made available for sale on nondiscriminatory terms, (2) whether griseofulvin should be licensed on reasonable terms, and (3) whether all forms of bulk sales restrictions in drug patent licenses should be enjoined.

In the five months since the government filed its brief and supporting affidavits, the defendants have come up with two new factual contentions which are set forth in their supporting affidavits: (1) the defendants' licensees do not sell in bulk, and (2) griseofulvin is already available to independent drug companies at a "commercially viable" price level. On the basis of these alleged facts, defendants argue that no injunctive relief is necessary, because their adjudicated antitrust violations have had no effect on the market and the market is already as pried-open to competition as is necessary or desirable. We disagree (1) as to defendants' facts, and (2) as to their logic. In the week and a half since defendants filed their affidavits, the government has caused subpoenas duces tecum to issue and sought information by affidavit to rebut these two allegations by defendants. Such rebuttal data as is in our

possession is appended hereto.[1] We believe that these factual allegations by defendants are contrary to the actual facts, and will reply first to these points. We will then reply to the principal legal and factual contentions of defendants relating to the three disputed aspects of relief listed above (p. 1). Finally, we will cover briefly in light of the foregoing the pertinent differences between the parties' respective proposed judgments, provision-by-provision. In this connection, we have attached hereto (Appendix A) for the Court's convenience a reprint of the two judgments in parallel columns, showing corresponding provisions side-by-side.

B.

Before so doing, however, a point given great stress by defendants requires clarification. This case was brought to secure an adjudication that the defendants' restrictions in patent licenses against the sale of drugs in bulk form were unlawful under the antitrust laws. Glaxo now argues (Br., p. 1) that this is only how the case was "originally brought"—and that "as ultimately submitted by plaintiff, however, the case presented only a far narrower and more conventional issue" of restrictions against resale of a purchased bulk commodity. In our view, this is only how defendants elected to submit their defense. The defendant ICI could have attempted, if it had wanted to, to defend against summary judgment, at least in respect to AMHO's microsize griseofulvin operations, by relying on *General Talking Pictures* v. *Western Electric Co.*, 305 U.S. 127

[1] The time available since defendants served their answering briefs and affidavits (Dec. 3, 1970) has been insufficient to permit the government adequately to check out the facts alleged in defendants' affidavits. Their licensees have experienced difficulty in producing subpoenaed data within the time allotted. The persons involved in the transactions referred to in defendants' affidavits have been difficult to locate and interview on short notice. Although we hope to serve and file all or a substantial portion of the above-described data prior to the December 17th hearing, the press of time may make it impossible to do so. At the same time, we do not wish to burden the Court with a further postponement of the hearing date. We therefore respectfully move for permission to file further affidavits or subpoenaed data within two weeks of the hearing date, should it be impossible for us to secure such material prior to the hearing. We anticipate, that all such matter would be rebuttal material corrobative of that material filed herewith.

(1938) (See Glaxo Br., p. 26).[2] Obviously, ICI considered *General Talking Pictures* a weak reed; at the same time, it did not want to defend on the basis of patents, because that would bring it within the *Gypsum* exception (referred to in this Court's prior opinion, 302 F. Supp. at 11-12, & nn. 89, 91), thereby placing in jeopardy the patents involved here. Consequently, ICI elected to defend on the basis that patents were immaterial, and "disclaimed any reliance on its patents" (302 F. Supp. at 10, n. 43; accord, *id.* at 12). In a nutshell, the defendants traded *General Talking Pictures* off to avoid *Gypsum*.[3]

The government does not want to take any unfair advantage of the defendants. If they now regret or assert that they did not understand the waiver (302 F. Supp. at 10, 12) and they now want to rely on their patents, two years and three summary judgment motions later, we will not stand in their way. But the price of revoking the waiver, and invoking *General Talking Pictures* and relying on their patents, is coming within *Gypsum*. That would mean that the parties would, at this late date, now go back to litigating the validity of the patents.[3] While it seems extremely late in the day to do that, we do not wish to appear to take any unfair advantage of a defendant, and therefore will not oppose a motion to reopen the issues. On the other hand, we cannot accept responsibility for defendants' tactical decisions. If they do not want to rely on their patents, then we cannot fairly be accused of submitting our case on the grounds that no patents, no manufacturing licenses, and no *General Talking Pictures* are involved. The case is now, as it was three years ago when it was filed, one aimed at preventing bulk sales restrictions in drug patent licenses, and at prying open the market

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[2] As shown in our opening brief on this motion (filed July 7, 1970, hereafter referred to as "Govt. Br."), at pp. 4, 5, 25-26, the licenses authorize manufacture, use, and sale; and Ayerst is, among other things, a manufacturing sublicensee of ICI, under the Glaxo microsize patent. It buys bulk regular griseofulvin, manufactures microsize griseofulvin therefrom pursuant to its sublicense, and then encapsulates and sells the drug. ICI could have argued, therefore, that the restraint was not one on alienation but on manufacturing.

[3] We would also argue, of course, that *General Talking Pictures* is inapplicable to bulk sales, as contrasted with field-of-use, restraints (see also Govt. Br., p. 29, n. 25); and that, if it is applicable, then the decision should no longer be regarded as binding and controlling authority. See, e.g., *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436 (1940); Govt. Br., p. 33, n. 26.

closed to competition by such restrictions. How the defendants wish to frame their defenses is and always has been up to them.

I. DEFENDANTS' LICENSEES DO SELL IN BULK.

The defendants seek to create the impression that the various agreements to prevent the sale of griseofulvin in bulk were futile and unnecessary activity of no significance —mere wasted ink on the contracts—because their licensees did not and therefore would not have sold in bulk.[4] Putting aside the relevance of the contention, and putting aside the non sequiter that "an agreement which merely reinforces barriers to entry" has no effect (compare 302 F. Supp. at 7, n. 16)—the fact is that substantial sales of bulk drug products have been made, and are at this time being made, by defendants' licensees.

In support to this argument, Glaxo served with its brief, among other things, an affidavit of a Schering officer which represents that Schering "does not consider itself to be in the business of selling bulk form drugs." Glaxo thus maintains that since Schering does not "consider itself" to be in the business of selling bulk form, it would not have sold griseofulvin—even absent the two companies' participation in the adjudged violation. Now it appears that Schering, contrary to its carefully worded affidavit, *does* sell substantial quantities of bulk pharmaceutical products. Indeed, according to the annexed affidavit of counsel for A. H. Robins Co., a substantial pharmaceutical house, in recent years Schering has annually sold Robins $300,000 and $400,000 worth of bulk brompheniramine mallate (an antihistimine sold by Robins as "Dimetane"[5]).

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[4] Glaxo has submitted affidavits from its licensees Schering and J&J to the effect, also, that such licensees would not have sold griseofulvin in bulk even if they had not jointly agreed with Glaxo not to sell in bulk. Significantly neither licensee denies the fact that the two of them negotiated jointly with Glaxo, and that they actively and successfully urged Glaxo to agree with them not to deal with Merck ("objected strenuously to Merck") lest Merck "press Glaxo continuously to permit general bulk sales" (see Govt. Br., pp. 7, and App. A thereto). Irrespective of whether this conduct constitutes an independent violation of the antitrust laws (see Glaxo Br., p. 7), this undisputed evidence certainly shows that Glaxo and its licensees intended the bulk sales restriction to be more than so much wasted ink in the contracts.

[5] Physicians' Desk Reference, p. 1082 (24th ed. 1970).

This is the only data on Schering's bulk sales the government now possesses. When Schering responds to the subpoena duces tecum previously served on it, we intend to file and serve the data listing Schering's other bulk sales.[6]

Similarly, AMHO sold in the very year it entered into the illegal agreement involved in this case, more of one product alone in bulk form than the amount of its griseofulvin purchases from ICI.[7]

II. GRISEOFULVIN IS NOT NOW AVAILABLE "AT COMMERCIALLY VIABLE PRICES"

Defendant ICI further argues (and has submitted affidavits to the Court in support thereof) "that (a) supplies of microsize griseofulvin in bulk and dosage form are available at commercially viable prices, within the framework of the existing ICI-Ayerst exclusive distributorship relation, and that (b) the generic houses do not require, as the plaintiff so unreasonably urges, access to ICI's bulk griseofulvin at the same price as is paid by Ayerst [$78 per kilo]" (ICI Br., p. 21). In support of this allegation, ICI makes two points. First, it seeks to establish the marketing success of Zenith and Owen Laboratories in distributing griseofulvin capsules that they have bought from Ayerst. Second, ICI takes issue with the Biocraft

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[6] It is noteworthy, however, that Schering's bulk sales of the one product alone, to one customer alone, are very substantial (cf. 302 F. Supp. at 7). Moreover, tabulated below are Schering's bulk brompheniramine sales to Robins for 1965-1967 (Robins Afft. ¶ 2) and Glaxo's bulk griseofulvin sales to Schering for the same years (Glaxo's Answers to Interrogatories No. 38-39) (filed with Wallace Afft. of 10/17/69):

Year	*Schering to Robins*	*Glaxo to Schering (Griseofulvin)*	
	(*Brompheniramine*)	*Regular Size*	*Microsize*
1965	$300,000	$211,000	$621,000
1966	$400,000	$136,000	$938,000
1967	$400,000	$227,000	$981,000

It is thus seen that Schering's bulk sales of brompheniramine to Robins are well in excess of Schering's bulk purchases of regular griseofulvin and nearly one-half of Schering's bulk purchases of microsize griseofulvin.

[7] Compare 302 F. Supp. at 7 ($200,000) with Second Supplemental AMHO Afft. $223,000 sales in 1962 of bulk Penicillin G, an antibiotic related to griseofulvin [an antibiotic produced by the microorganism Penicillium griseofulvum]; over $50,000 sales of five other bulk drugs).

affidavit ("Biocraft Afft.") previously filed in this case, and attempts to show that Biocraft is able to make a handsome profit on griseofulvin purchased from Ayerst. ICI errs on both counts, as we shall now show.

A. *The Marketing Success of Zenith and Owen*

ICI's Ayerst Afft. states that Zenith purchased 500,000 capsules from Ayerst on June 24, 1969, and another 500,000 on October 9, 1970. This would indicate a consumption of no more than (and possibly less than) 500,000 capsules over the more than 15-month period involved, which represents about ½% of United States griseofulvin sales—hardly an impressive figure. The Ayerst Afft. also points to a sale of 1,000,000 capsules to Owen Laboratories, over a year and a half ago. Owen's total sales of griseofulvin to date add up to approximately $96,000;[8] which represents about 1% of the annual national market.

It is plain, then that in actual fact, there is nothing "commercially viable" about Ayerst's sales to these small competitors. This is conclusively established by the annexed affidavit of Owen Laboratories (hereafter referred to as "Owen Afft.")

Owen, a small independent pharmaceutical house specializing in dermatological products,[9] became interested in griseofulvin because the product appeared "ideal" for a drug house of Owen's type (Owen Afft., ¶ 6-8). Owen, therefore, after ICI advised the Court that it would grant reasonable royalty licenses, contacted counsel for ICI and secured a license. ICI advised Owen, however, that griseofulvin would be available to it only from Ayerst (Owen Afft., ¶ 9).

Owen then contacted Ayerst, which declined to sell griseofulvin in bulk to Owen; Ayerst would agree only to sell Owen 250 mg. capsules at $46.30 per thousand, in minimum orders of 500,000 capsules (Owen Afft. ¶ 10), as opposed to the commercially superior 500 mg. tablets (Owen Afft. ¶ 11). As is explained in detail in the Owen Afft. (¶¶ 12-13), this price results in Owen losing $2.30 on every

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[8] Owen Afft., ¶ 16.

[9] Owen is not a generic seller; it markets under its brand names (e.g., "grisOwen"), as do the defendants' established licensees, Ayerst, J&J, and Schering (Owen Afft., ¶ 5).

bottle of griseofulvin capsules it sells, and Owen's marketing costs alone exceed the amount of return on the product. Despite the allegedly "commercially viable prices," griseofulvin is the only unprofitable product in Owen's active line (Owen Afft., ¶ 13). Because of the pricing structure, Owen is unable to promote griseofulvin aggressively, or compete in terms of price, and it has been able to capture only 1% of the market, although on comparable other products it normally achieves a market penetration of 10% or 20% (Owen Afft., ¶ 16).

Owen emphatically denies that griseofulvin is available to it at "commercially viable prices." It says that it is losing money on the capsules it buys from Ayerst, and that it would still lose money even if it purchased bulk microsize griseofulvin at $135 per kilo (Owen Afft., ¶ 19).[10] Owen states that it will probably continue to carry the product, anyhow, to maintain prestige and a full dermatological line, but Owen will never become anything but "a very minor factor in this market, given the present distribution system" (Owen Afft., ¶ 20). In contrast, Owen states it could successfully market the product as it originally planned, given a nondiscriminatory price, thereby giving the public and medical profession the benefits of lower prices and better service (Owen Afft., ¶ 21).

In short, the record facts are diametrically opposite to ICI's cheerful assumptions of "commercially viable prices" which obviate the need of bulk sales relief in this case.

B. *Biocraft's Description of Marketplace*

ICI characterizes the Biocraft Afft. previously filed in this case as "inaccurate" (Br., p. 22). In that affidavit, Biocraft's president demonstrated how the previous Ayerst offers to sell griseofulvin to generic houses were illusory, because the quoted price was so high that the generic house was squeezed into a no-profit-margin situation. According to ICI, Biocraft has made some mistakes in its calculations, with the alleged result that Biocraft really "is in a position to sell the capsules to a distributor at $76.30 per 1,000, which would give the distributor a 32% spread of the re-

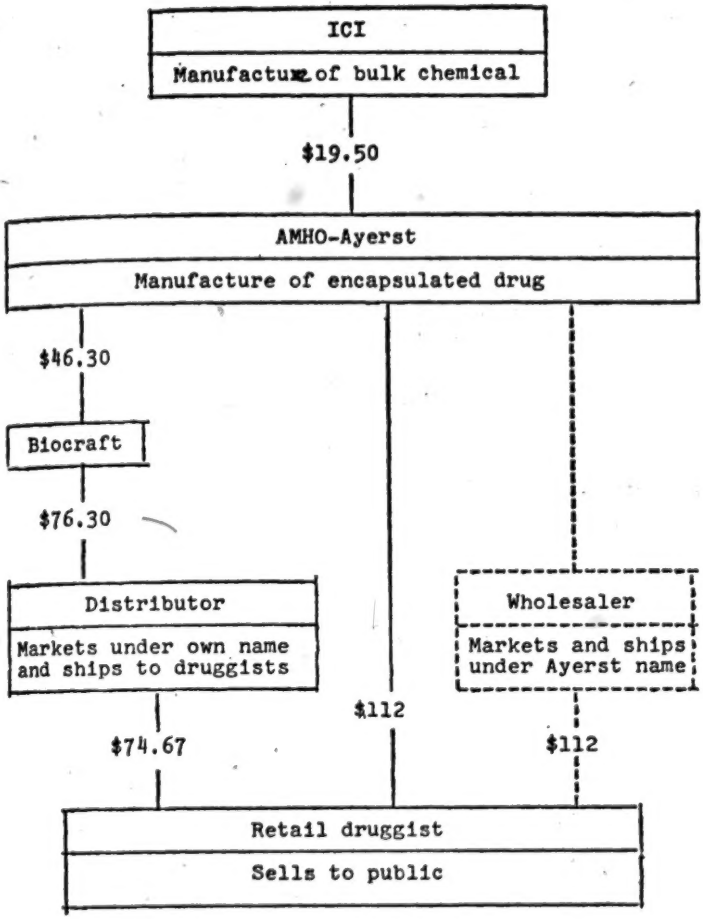
[10] We note that Ayerst has never offered bulk microsize griseofulvin to Owen (Owen Afft., ¶ 19), despite ICI's present claims that bulk microsize griseofulvin is freely quoted to interested parties.

tail price—a rather close approximation to the 33⅓% taken out of the air by Biocraft." Accordingly, ICI corrects 'Biocraft's erroneous figures' and allegedly establishes the proposition that the generic drug houses will not suffer any price squeeze even though they are denied "access to ICI's griseofulvin at the same price as is paid by Ayerst."

The trouble with ICI's "new mathematics" is that ICI has completely ignored one of the levels of distribution in order to arrive at its putatively handsome profit margin. This mistake is explained in the further affidavit from Biocraft's President (hereafter referred to as the "Second Biocraft Afft.") appended hereto; the same is also shown graphically in the diagram on the following page of this brief. ICI's computations are based on the misconception that Biocraft is a wholesaler or a distributor, selling directly to the retail druggist (compare first Biocraft Afft., ¶¶ 4, 10). Biocraft is not; it is a generic manufacturer. As such, Biocraft sells products in finished dosage form to distributors—and the distributors resell to the retail druggist under the distributors' names and labels (Second Biocraft Afft., ¶ 2).

Therefore, even accepting ICI's calculations, when ICI says that "Biocraft is in a position to sell the capsule to a distributor at $76.30 per 1,000" and this "would give the distributor a 32% spread of the retail price—a rather close approximation to the 33⅓%," (ICI Br., p. 23), ICI is either confusing the distributor with the retail druggist or it is ignoring the fact that, as the previous Biocraft Afft. and the Second Biocraft Afft. point out, Biocraft must sell to a distributor who must resell Biocraft's "Brand X" to a druggist at no more than two-thirds the brand name price, in order to induce the retail druggist to carry the "Brand X" product. In terms of dollars and cents, this means that when the established licensees of defendants sell to the retail druggist at $112 per thousand, Biocraft's customer (the distributor) must sell at two-thirds that price or less —$74.67.

At the same time, ICI contemplates that Biocraft will sell to the distributor at $76.30 (ICI Br., p. 23), or $1.63 more than the distributor is to receive. As the President of Biocraft puts it, "this means that if a distributor sold to the retail druggist at a minus 1⅓% profit, then he could induce the retailer to carry my product" (Second Biocraft



PRICE AND DISTRIBUTION STRUCTURE FOR GRISEOFULVIN AMHO OFFERS IN DOSAGE FORM AT $46.30 PER 1000, PER ICI BR., pp. 22-23

Note: All prices are on a basis of 250 mg., in 1000's.

Afft. ¶ 4). In short, despite ICI's "new mathematics," the reality of the marketplace is that "it is impossible for me [Biocraft] to buy griseofulvin in capsule form from ICI's distributor [Ayerst] and resell the griseofulvin except at a loss" (Second Biocraft Afft., ¶ 4).

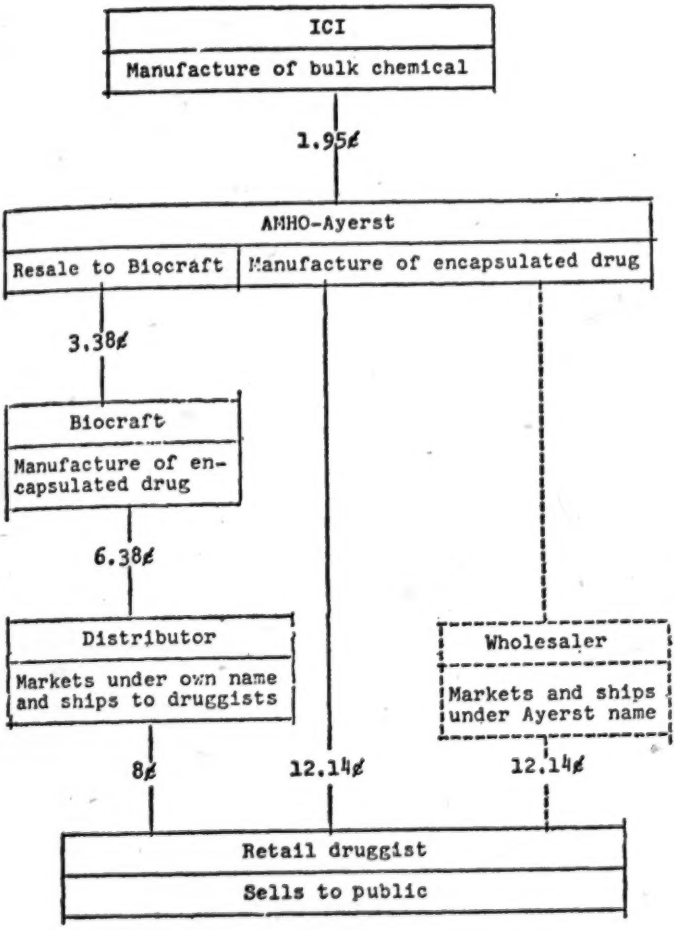
A similar misconception deflates ICI's claim that micro-size griseofulvin at $135 per kilo is a "commercially viable" price. As the President of Biocraft shows (Second Biocraft Afft. ¶ 3), this price is much too high to permit formulation and generic distribution of the product at a price to the retail druggist which is competitive with the defendants' licensees. Biocraft's statements on this point are shown graphically on the diagram on the following page of this brief.

It is thus clear that griseofulvin is still not "available" to independent drug houses in any realistic sense. No independent has been able to penetrate the market to even a perceptible degree, against the deeply entrenched position of the defendants' licensees, because no independent can buy the drug at less than an exhorbitant price. There is no hope for any change under the present market structure. Unless bulk sales are decreed by this Court, this market will remain closed to competition as it has been, for over a decade, since defendants embarked upon their illegal course of conduct.

III. BULK SALE RELIEF IS NECESSARY

A.

We have shown in our first brief, and earlier in this brief, that there is a manifest need for bulk sales relief. Until the government took antitrust action against the defendants, they prevented the sale of griseofulvin in the United States by unlawful agreements with their licensees and with one another. The defendants have consistently refused to sell griseofulvin in bulk to generic drug houses and other independent sellers. At the same time their three exclusive distributors in the United States have also refused to sell the drug in bulk. Recently, one licensee (Ayerst) has made offers to sell griseofulvin in bulk, but the prices quoted are so high as to make the offer an illusory one. And the remaining licensees (Schering and J&J) have declined to make even illusory offers to sell the drug.



PRICE AND DISTRIBUTION STRUCTURE FOR GRISEOFULVIN AMHO OFFERS IN BULK AT $135 PER KILO IN 250-KILO LOTS

Note: All prices are on a 250 mg. basis, per capsule, in cents. For a 100's basis, convert to dollars by multiplying cents by 100.

Griseofulvin continues to travel from the defendants to their established licensees, wrapped in a competition-free package.

The defendants and their licensees now file affidavits saying that they would not have sold griseofulvin in bulk, even if they had never entered into a combination to prevent bulk sales. This allegation is made in the face of the fact that defendants' licensees have sold other drugs in bulk (Part I of this brief), and the fact that Ayerst now (supposedly, as a result of ICI's unleashing it) does offer to sell griseofulvin in bulk.

The defendants' licensees deny in their affidavits that they were influenced in any way, in their past or present decisions not to sell griseofulvin in bulk, by their agreements with the defendants. The licensees do not deny, however, that they knew very well that the defendants were licensing them all on the same basis, subject to the same bulk sales restriction; they do not deny that they jointly negotiated with Glaxo the license agreement containing the bulk sales restriction; and they do not deny that they "strenuously" opposed Glaxo's granting a griseofulvin license to another drug company (Merck), lest that company "press Glaxo continuously to permit general bulk sales" (Govt. Br., pp. 3, 7, App. A). In short, what the defendants' licensees fail to deny in the affidavits annexed to defendants' briefs is more significant than what they do deny.

In the wake of this long history of concerted activity, the defendants ask the Court to believe that the slate has been wiped clean by the defendants' notifying their licensees that the bulk sales restriction would no longer be enforced. The fact that the licensees still refuse to sell griseofulvin in bulk, or that they are willing to sell it only on such terms as to make the offer no real offer at all, is now alleged to be merely the coincidental result of unilateral decisions by the licensees. We submit that this contention is unbelievable; it is contrary to common experience.[11]

At this point, an order that merely required defendants to conspire no longer would be like an order to someone

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[11] Compare *International Sale Co.* v. *United States*, 322 U.S. 392, 400 (1947): "The District Court is not obliged to assume, contrary to common experience, that a violator of the antitrust laws will relinquish the fruits of his violation more completely than the Court requires him to do."

poking holes in a tire with an ice pick that he should cease from applying the ice pick to the flat tire. What is needed is to patch the tire and reinflate it. That is the kind of relief needed here and sought in the government's proposed judgment.

B.

Short Supplies. The defendant ICI argues that its status as a British corporation entitles it to special exemptions from antitrust relief. It says, first, that ICI is in the griseofulvin business on a worldwide scale and that it "periodically encounters difficulties in supplying this worldwide demand from its limited facilities" (Br., p. 16). ICI goes on to say that it would therefore be "manifestly unfair and harsh" to impose on it the obligation to sell to generic drug houses and independents on a non-discriminatory basis. We submit that the possibilities of short supply further underscore, rather than detract from, the necessity for compulsory relief as to sales. If the generic houses and other independent sellers are to be whipsawed periodically and discriminatorily in times of short supply, the barrier to their effective entry into the market will be raised still further.[12] In any event, ICI's possible supply problems furnish no basis for withholding otherwise proper relief from the public, for the government seeks to impose no further burden on ICI than that ICI treat all customers on a reasonable and non-discriminatory basis, whether by equitable rationing or otherwise. Accordingly, the decree proposed by the government would not impose any "unfair and harsh [burden] from a practical standpoint" (see ICI Br., p. 16).

Extraterritoriality. ICI also asserts, but Glaxo does not, that such a decree also would involve "an extraterritorial reach of jurisdiction" (Br., p. 17), beyond the power of this Court. Nothing could be further from the fact. The decree proposed by the government would not compel ICI to export from England; it would not compel ICI to sell at all. The proposed decree would be purely negative in

[12] It should be noted that Ayerst has, on past occasions when it quoted griseofulvin to an applicant therefor, cautioned it that the offer to sell might be withdrawn at any time because of short supply, or even declined to sell on the basis that Ayerst had insufficient supplies (see exhibits attached to Schulz Afft. appended hereto).

impact, enjoining ICI from refusing to sell to independents *if* ICI elects to sell to the established United States firms. The only obligation on ICI would be one to refrain from discriminating among large and small United States buyers.

Price discrimination. ICI contends, further, that it should not be required to sell bulk griseofulvin to the generic houses and independents at the same price ($78 per kilo) that it charges AMHO (Br., p. 17). ICI says that these small companies do not deserve the same price as AMHO, because of the latter's alleged years of investments in money, time, research, and advertising, and in otherwise developing a nationwide market for griseofulvin and other drugs (Br., pp. 18-19). Curiously, when the government last week sent AMHO a subpoena duces tecum, calling for the books and records as would disclose each of the items of research, development, and other allegedly "vitally important and necessary functions" carried on by AMHO (but allegedly not carried on by the generic houses and other independents), together with the dollar amounts thereof applicable herein—it turned out that AMHO did not have any books and records that would disclose such information (see Supplemental AMHO Affidavit appended hereto). It would appear therefore, that there is no documentary evidence to support ICI's theory that big companies that advertise themselves extensively deserve a lower price than small companies.

Price fixing. Finally, ICI concludes with the allegation that the proposed compulsory relief respecting sales would put the Court "into the business of fixing prices for an industry, or determining margins of profit as between different classes of vendors performing incommensurable and completely disparate services" (Br., p. 24). The government's proposed judgment would do nothing of the kind, just as the Supreme Court did nothing of the kind in decreeing such relief in the *Besser* case, the *International Salt* case, and the *United Shoe* case.[13] That such price fixing is the purpose or would be the effect of the judgment proposed herein is conclusively refuted by the statement of Biocraft's President (Second Biocraft Afft., ¶ 6):

> In reading over the papers in this case, it seems to me that the defendants are trying to give the Court

[13] See Govt. Br., pp. 15-18 and n. 15.

the impression that Biocraft or other generic sellers of drugs want the Court to go into the business of fixing prices for the industry for [or] determining margins of profit as between us and the brandname sellers. Nothing could be further from the truth. Speaking for Biocraft, at least, I assure the Court that we do not want anything of the kind. All we want is to be treated without discrimination. We don't want the Court to determine what price ICI will charge Ayerst or what Ayerst will charge us or anybody else. What we request is that, as buyers, we be treated on a fair, equal, and non-discriminatory basis —rather than that the defendants follow the principle that big companies deserve a lower price than small ones, such as ourselves.

IV. REASONABLE ROYALTY LICENSING IS NECESSARY AND APPROPRIATE RELIEF HERE

A. *The Griseofulvin Market Drastically Needs Prying Open.*

The government has demonstrated, with affidavits from a number of businessmen actually in the market, their inability to compete with the entrenched position enjoyed by the licensees of the defendants.[14] Clearly, the government has established beyond question of doubt that relief is necessary to open the griseofulvin market up to competition, and that without relief the public will continue to be deprived, as it has for the decade since defendants began their unlawful combination, of the benefits of competition.

Glaxo and ICI are monopolists in the strictest sense of the word. These two English companies are the sole source of all the griseofulvin consumed by the United States public. Purchasers in the United States appear to be completely dependent on the policies of these companies. Even the American parties to the illegal agreements (such as AMHO) appear to suffer, or at least allege that they suffer, "severe shortage in which the certainty of supply is questionable" (Schulz Afft., Ex. 4A). Indeed, ICI concedes that it periodically encounters difficulties in supplying [its]

[14] See Owen Afft., Biocraft Afft., Second Biocraft Afft., Dooner Afft., Zenith Afft.

. . . worldwide demand'' (ICI Br., p. 16). Defendants say that compulsory sales relief would obviate all necessity for licensing relief, but there is every reason to believe that the defendants will have their own order of priorities in meeting their worldwide demand, and that at times the effect will be a shift that would make supplies to the American market even more critical than they are now or have from time to time been alleged to be. Thus to assure that relief to the American market is not a vain promise, compulsory licensing, as well as compulsory sales, is necessary to insure an adequate American supply of the drug.

Glaxo argues that compulsory licensing is warranted only if both defendants cease selling in the United States. Even if this contention were valid, as applied to manufacturing processes or the like for griseofulvin generally, the argument overlooks Glaxo's patent monopoly over microsize griseofulvin. Since ICI does not sell microsize griseofulvin in the United States, any purchasers from ICI must infringe (unless either defendant will grant a license or sublicense on microsize, which they refuse to do) Glaxo's microsize patent to make and sell the commercially superior microsize griseofulvin. Thus merely Glaxo's refusal to sell to the United States would in effect foreclose microsize griseofulvin from the United States market except to the extent that it could be purchased from Ayerst, which is sublicensed by ICI under the microsize patent. An order for compulsory sales cannot, of course, be entered against Ayerst, a non-party. The only alternative, therefore, is to order compulsory sublicensing of the microsize patent by ICI or else compulsory licensing by Glaxo. Otherwise, if Glaxo ceases selling, whether or not ICI continues to sell, microsize griseofulvin could no longer be assured to the American market.

Another, perhaps more serious problem is that defendants indicate that they may be incapable of continuously meeting the demand for griseofulvin in the United States, as pointed out above.

Finally, defendants attempt, somewhat inartfully, to paint the government's contentions as premised on the motion that the need for compulsory licensing is conditioned upon a finding of the need for compulsory sales. Such a view is, indeed, not the position of the government and the Court clearly should reject it. The government does now and has

previously vigorously urged *both* compulsory sales and compulsory licensing relief. If, for some reason, the Court should deny compulsory sales relief, the government would even more vigorously urge, then, the stark necessity for compulsory licensing of griseofulvin patents and technology on a reasonable royalty basis. Such relief, then, would have to be relied on to bear the full burden alone, of unlocking this market which has for so long been so tightly closed to the forces of competition.

B. *The Court Has Full Power and Authority to Order Compulsory Licensing.*

Glaxo suggests that the Court is without power to decree reasonable royalty licensing in this case, because "to guarantee the continued availability of griseofulvin in the American market [would be] to deny defendants an essential ingredient of their rights under the patent system" (Glaxo Br., p. 23). Glaxo then cites and relies upon *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 429 (1908), and *Leuscher v. Kuther*, 314 F. 2d. 71, 73 (9th Cir. 1963), for the proposition that defendants have an absolute right to keep this drug off the American market and deny its use to citizens of this country.

The *Paper Bag* case, far from supporting Glaxo's position undercuts it. That case involved not drugs or another publicly essential product, but a mechanism for making square bottoms for paper bags. The Supreme Court decided that, in the circumstances involved, where there was no record evidence of the character or effect of nonuse of the patent, such nonuse would not furnish any defense for an infringer. The Court then went on to state, on the page following that cited by Glaxo (*id.* at 430):

> Whether, however, a case cannot arise where, regarding the situation of the parties in view of the public interest, a court of equity might be justified in withholding relief by injunction, we do not decide.

The question expressly reserved in the *Paper Bag* case was decided in *City of Milwaukee v. Activated Sludge, Inc.*, 69 F. 2d 577 (7th Cir. 1934). In that case the Court of Appeals refused to enjoin the City of Milwaukee from infringing patents covering the operation of a sewage treatment plant. The Court said that to grant an injunction

would result in pollution of Lake Michigan, and endangering the health and lives of the local citizenry (*id.* at 593). It therefore ruled that patent rights should be subordinated to the public interest. The Court did, however, allow an accounting to be awarded; this is, of course, the direct analogue of compulsory, reasonable-royalty licensing.

Similarly, in *Vitamin Technologists, Inc. v. Wisconsin Alumni Research Foundation*, 146 F. 2d 941 (9th Cir. 1944), the Court of Appeals ruled that the public interest was violated when a patentee refused to license, but tried legally to enforce, his drug patent (covering the process of producing vitamin D by ultraviolet radiation). The Court pointed to the above-quoted language from the *Paper Bag* case and concluded therefrom that the patentee could not be allowed to enforce the patent. The Court then went on, also, to refer the matter to the Attorney General of the United States for appropriate action to protect the public interest.

Thus, it is seen that the authorities are squarely opposed to defendant's position. To the contrary, they hold that refusal to use a patent, where the public interest (such as public health) is adversely affected thereby, will deprive the patentee, at the very least, of the right to injunctive relief. Infringers will, instead, be allowed to practice the invention, with their maximum liability being to account to the patentee for the use of the invention (i.e. compulsory licensing).[15]

Finally, the fact that both defendants elected not to predicate their defenses on their patents is immaterial to whether such patents should be the subject of compulsory licensing. The minimum consideration in determining the appropriateness of compulsory licensing, as has been pointed out before, is whether the previously restrained market can be effectively pryed open without compulsory licensing, not what the defendant's theory of the case is. If defendant's approach were adopted, it would become possible to enter compulsory licensing relief against patent holders for unlawful licensing practices only when such defendants decided that they had sufficiently good a chance

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[15] Whatever relevance the Kuther case, involving sardine canning machinery, may have in the drug context—the ruling there that the patentee could keep the machine out of use during the life of the patent was reversed by the Supreme Court, 377 U.S. 422 (1964).

to prevail in the action by relying on their patent that this warranted their risking such relief. Clearly, the Court should not be bound in its determination of what constitutes adequate relief by the strategems of defense counsel in calculating the contingencies of risk against cost.

V. RELIEF AGAINST BULK SALES RESTRICTIONS OF ANY TYPE IS PROPER AND NECESSARY

As shown in Part B of the Introduction, *supra*, two years ago the defendants elected not to rely on their patents, in the course of a strategic trade-off to avoid the government's challenge to the validity of such patents. Glaxo now seeks to rely on its patents and the decision in *General Talking Pictures* v. *Western Electric Co.*, 305 U.S. 124 (1938), in order to preserve the very bulk sales restrictions contained in its Schering and J&J licenses; ICI takes a similar position respecting the bulk sales restriction contained in its AMHO license. The *General Talking Pictures* defense permits the owner of a valid patent to impose certain otherwise objectionable restraints on the use of products manufactured by a licensee—the rule exists in order to accommodate the policy of the antitrust laws with the monopoly reward policy of the Patent System. It is therefore arguable that the following situation, which took place in this case, is within the *General Talking Pictures* defense: ICI sells griseofulvin to AMHO in regular form; ICI sublicenses AMHO under Glaxo's microsize patent to manufacture microsize griseofulvin from the regular griseofulvin by grinding (micronizing) it up into small particles; ICI also restrains AMHO from selling in bulk such microsize griseofulvin so manufactured. As indicated, however, the defendants elected not to rely on such a defense to this suit.

The defendants now seek to transform in some way their waiver of a defense into an alleged choice by the government "to remove this issue from the area of controversy" (Glaxo Br., p. 26). Defendants now advance the bizarre claim that the government "consciously decided not to challenge on the merits" the defendants' practices allegedly falling within the umbrella of that defense. We do not see how defendants can parlay their unwillingness to put the validity of their patents on the line (by choosing not to invoke such patents as a putative defense to this

antitrust suit) into a shield for any restraints that could be defended in the name of patent protection and the *General Talking Pictures* doctrine.

If ICI wanted to rely on the patents to defend the above-described restraint, then ICI should have done so just as Ethyl did in *Ethyl Gasoline Corp.* v. *United States*, 309 U.S. 436 (1940)—see Govt. Br., p. 33 and n. 26[16] (By the same token, we would have made the arguments the government made in *Ethyl*.[17] But that is all past history. ICI did *not* choose to rely on its patents. ICI did *not* choose to argue, as it might have, that the restriction on AMHO's bulk sales was more than a mere restraint on alienation—and that it was sheltered under the *General Talking Picture* defense because of AMHO's manufacturing (grinding into microsize particles) activities as ICI's sublicensee under the Glaxo microsize patent. In these circumstances, the government can hardly now be taxed for failure to challenge a defense that ICI never chose to make. We did not "remove this issue from the area of controversy by ultimately restricting [our] contentions" (Glaxo Br., p. 26)—on the contrary, the defendants restricted their defense contentions. That is, of course, their privilege. But such defensive action on their part should not insulate them from prohibitory relief against the very acts they and their licensees agreed to do and did—namely, in the case of ICI and AMHO, enter into a patent license agreement pursuant to which: ICI sold AMHO bulk regular griseofulvin, and AMHO manufactured the same into microsize griseofulvin pursuant to a sublicense under the microsize patent—all subject to a restriction that AMHO should sell such microsize griseofulvin only in dosage form and not in bulk.[18]

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[16] Ethyl argued that the restriction was restraint on alienation only when viewed from the standpoint of Ethyl's sales of patented tetraethyl lead fuel additive. When Ethyl's patents (1) on the motor fuel its vendees made by mixing gasoline with additive and (2) on the use of such fuel in an engine were also considered, then the restriction had to be viewed (Ethyl said) as a permissible manufacturing restraint (i.e., one within the General Talking Picture defense). The Supreme Court did not agree.

[17] We would also have made the *Gypsum* challenge that this Court expressly authorized, 302 F. Supp. at 15; and made the other arguments indicated, *supra*, p. 4, and Govt. Br., pp. 29-30, n. 25.

[18] As this Court has previously found, ICI imposed this restriction on AMHO by agreement with Glaxo.

The Court therefore should, we submit, prohibit in its final judgment the suppression of bulk sales by means of patent license agreements, whether they are in the form of restraints on the resale of patented goods, restraints on the sale of patented goods subjected to manufacturing processes after their purchase from the licensor (AMHO's arrangement), or otherwise—(1) because that is what the defendants did here, (2) in order to issue a decree without loopholes that could cause the Court to be repeatedly involved in interpretation or modification proceedings, and (3) to insure that this market which has been closed to competition for more than a decade by defendants' unlawful restraints will be pried open to give the public, at last, the benefits of free and open competition in these goods.

TEXT COMPARISON

The following is a paragraph-by-paragraph comparison of the two proposed judgments, on those points where they differ. We have appended hereto (Appendix A) a side-by-side comparison of the two texts to facilitate the Court's examination thereof.

A. *Preamble*

The government has presented as short a preamble paragraph for the judgment as it thought possible, to avoid covering any controversial, or legally operative or significant, points therein. Such matters are set out, instead, in separately numbered and lettered points below in the government's proposed judgment, where the Court may select or reject the same, as it may in its discretion deem appropriate. See ¶ II.

The very long preamble proposed by the defendants is, in contrast, unnecessarily argumentative and, we believe, misstates or incompletely states the nature of the Court's prior rulings. For example, defendants say that the Court ruled that the government "had no standing to attack the validity of patents." We believe that the Court ruled (302 F. Supp. at 15), instead, that the government lacked standing to challenge validity, unless the case came within the "fraud" or "Gypsum" exceptions, so that *on the basis of the facts pleaded* herein, and only on such basis, the government lacked standing. Since there is a significant

legal distinction involved, we believe that defendants have incorrectly stated the Court's prior ruling.

B. *Definition of "Drug"*

The defendants seek to exclude *intermediates* from the definition of "drug," thereby leaving themselves free to engage in restraints on the alienation of any chemicals requiring even the slightest alteration by the purchaser thereof to convert it into "drug" form. Our concern is with those products which are shipped in commerce in a technically nonpharmaceutical form for commercial or other reasons. For example, sodium diatrizoate (a product involved in one of the government's other drug license cases) is not shipped as such for cost reasons. Instead, it is shipped in bulk as diatrizoic acid powder; the purchaser converts the acid into a sodium salt solution thereof (the drug administered to the patient); and he packages the solution into dosage form. Similarly, ampicillin (a product involved in another of the government's drug license cases) may be sold or shipped in bulk form as its non-drug intermediate, 6-aminopenicillanic acid.

For these reasons, we do not think that relief which even the defendants concede is proper (Glaxo Br., p. 18; ICI Br., pp. 30, 40) should be evaded by the device of placing the restraint on the intermediate instead of the final product. On the other hand, we have no desire to secure relief in this decree, as defendant ICI seems to imagine, against restraints on the alienation of industrial chemicals not intended for pharmaceutical use. We do not think that the language we have proposed lends itself to that interpretation, but we have no objection to adding a further provision, if the Court deems it desirable out of abundance of caution, to the definition, as follows: "provided, however, that this definition shall not embrace any product which is intended for use as, or transformation into, a product the end use of which is not within the meaning of § 321(g)(i)". Such language should both meet defendant's problems, if any, and protect the integrity of the Court's decree against evasion thereof.

C. *Declaration of Violation*

The government's and defendants' declaration-of-antitrust violation paragraphs (¶¶ II-A and III-B, respectively)

appear to differ principally in that the government states that the defendant's agreements were made with parties who were both purchasers *and* patent licensees, while defendants refer to their licensees solely as "purchasers." The difference relates to whether this is a bulk sales restriction case or a bulk sales restraint on alienation case. We have briefed our view of the case, *supra* (Introduction, Part B). For the reasons given there, we submit that our form of language is more correct.

The government, but not the defendants, proposed language (¶ II-E) expressly referring to, incorporating, and making final the four prior interlocutory orders on substantive issues. Not only does this make for a more orderly and coherent record (with one Final Judgment tying together in one place all prior orders), but, we submit, it avoids accidental ambiguity and contradiction between this order and prior orders. We therefore submit that this paragraph is desirable and should be included.

D. *Persons Bound by Judgment.*

In ¶ II the defendants add to the government's proposal the following sentence: "For the purpose of this Final Judgment, such defendant and its subsidiaries, directors, officers, agents and employees shall be deemed to be one person." The defendants offer no word of explanation of this language or reason for its inclusion. We do not understand what defendants' purpose is in offering this provision. If that purpose is to overrule or contravene the rulings of the Supreme Court in *U.S.* v. *Yellow Cab Co.*, 322 U.S. 218 (1947), and *Keifer Stewart* v. *Joseph E. Seagram & Sons, Inc.* 340 U.S. 211 (1951) then the government would take strong exception thereto. In any event, the cryptic language is undesirable because it is unnecessary.

E. *Injunctive Relief*

Restraints on alienation. ¶ IV-A of the government's proposed judgment is a prohibition against entering into, obeying, or enforcing any agreement to restrain the alienation of drugs. In their respective briefs (Glaxo, p. 18; ICI, pp. 30, 40) the defendants concede the propriety of such relief and state that their proposed judgment contains language "similar" to the government's. Their ¶ IV-A,

however, is verbose, confusing, and reaches a variety of particular restraints on alienation never involved in this case and as to which the government has never sought relief against the defendants. Defendants' ¶ IV-A forbids use of restraints on alienation: to allocate geographic market areas in the United States, to allocate consumer end uses, to limit concentrations or formulations, and to prevent reshipment to foreign countries. Defendants do not explain why they want an order to issue against themselves forbidding such conduct. It would appear that they have copied the language from some other decree in which such provisions were perhaps relevant, unlike here, where they have no conceivable relation to the facts of this case. In any event, the government has neither sought nor desires the entry of a judgment focused on such irrelevant conduct.

Refusal to deal. Defendants' ¶ IV-B forbids use of refusal to deal to accomplish that which is forbidden by ¶ IV-A. The government's draft lacks such a provision. However, the defendants are right, and we are wrong in failing to include such language. We therefore concur in the inclusion in the judgment of the language set out in defendants' ¶ IV-B. We assume, however, that "resell" is a typographical error for "sell" since the instant defendants violated antitrust laws by selling, *not* reselling, subject to a bulk sale restriction; this error should be corrected.

Labelling. The defendants propose a prohibition against their use of labels on packages, purporting to create restraints on alienation (¶ IV-C). The government has no corresponding provision in its draft. The record in this case shows no instance of such conduct, and even the most excessively suspicious prosecutor could hardly expect defendants ever to engage in such a bizarre maneuver. This is apparently another instance of defendants' blind adoption of language from some other decree relating to some other scheme to restrain trade, but which is wholly irrelevant to the instant defendants' violation of the Sherman Act. Again, we have never sought nor now desire such a prohibition.

Agreements to impose restraints on third parties. The government's ¶ IV-B and the defendants' ¶ IV-D are each directed to agreements, such as the one existing between Glaxo and ICI, to impose a restraint on alienation on a

third party. Defendants' draft is limited to "agreements," while the government's also forbids "understandings." The government's language also deals with obeying or enforcing preexisting such agreements, or understandings, rather than deal only (as do defendants) with future agreements. The government's draft, we submit properly forecloses loopholes which defendants' language creates.

F. *Sales and Licensing Relief*

¶¶ IV-C through IV-H and ¶ V of the government draft deal with sales of griseofulvin, licensing of griseofulvin patents, and bulk sales restrictions on drugs. This matter is briefed in detail earlier herein.

G. *Compliance*

The government's ¶ VI and defendants' ¶ V deal with compliance with the decree. In ¶ A, defendants apparently seek to limit the government to using a single representative to investigate compliance. In ¶ B defendants seek to permit only "necessary" reports of compliance, presumably requiring the Court to become involved regularly in passing on "necessity" of particular reports. Finally, in the government's ¶ C judgment compliance information may be disclosed to IRS or other duly authorized parts of the Executive Branch, while defendants would prohibit such disclosure. The government's form is standard language taken from judgments and consent decrees long adopted by Courts throughout the country.

H. *Duration*

In some exceptional circumstances the government has, in negotiating the terms of consent decrees of unlitigated cases, agreed to limitations on the duration of relief. But such limitations are extremely rare and are agreed to only upon the strongest showing justifying such limitations. Here, in contrast to such circumstances, the government is not attempting to hammer out a decree in order to settle a yet untried case, but to obtain adequate relief for violations that the Court has squarely found to contravene the antitrust laws. Indeed, the violations here are so clear and undisputed that they have been adjudged to be *per se* violations, on motions for summary judgment. It is difficult to

conceive more compelling circumstances for entering an injunction that is not bounded by some arbitrary termination date.

If in some way conditions should ever alter sufficiently to warrant changing the decree, the Court retains jurisdiction and the parties may petition it that the order be modified. Moreover, the government, in an effort to avoid any possible claim that relief is too onerous, has in its proposed judgment limited the provisions decreeing mandatory sales to ten years. Thus, clearly there is no basis for an across-the-board limitation of the duration of this decree to ten years, as suggested by defendant.

I. *Costs*

The defendants inexplicably omit costs from their proposal. Clearly, as losing parties, they should be taxed with the government's costs. Accordingly our ¶ VIII simply provided for such costs.

Respectfully submitted,

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Dated: December 15, 1970

SUPPLEMENTAL MEMORANDUM OF DEFENDANT ICI ON RELIEF, FILED DEC. 17, 1970

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, PLAINTIFF, v. GLAXO GROUP LIMITED and IMPERIAL CHEMICAL INDUSTRIES LIMITED, DEFENDANTS.	Civil Action No. 558-68

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, PLAINTIFF, v. GLAXO GROUP LIMITED and IMPERIAL CHEMICAL INDUSTRIES LIMITED, DEFENDANTS.	Civil Action No. 558-68

SUPPLEMENTAL MEMORANDUM OF DEFENDANT ICI ON RELIEF

At 8:00 p.m., December 15, counsel received from the plaintiff its Reply Brief (longer than its original Pre-Hearing Brief of July 7, 1970) accompanied by seven affidavits (the original Brief had only four) and a large number of documents. Prior to that, the only knowledge ICI had from plaintiff as to the issues that would be raised in these papers was plaintiff's oral statement over the telephone that plaintiff was seeking, if it could, to establish three points:—

(1) That Glaxo's and ICI's vendees (e.g., Ayerst) were selling bulk drugs;
(2) That the prices quoted by Ayerst for griseofulvin were not commercially viable; and
(3) That the market for griseofulvin was not a contracting market.[1]

These three factual points, which relate to issues raised at the outset of this litigation, should have been dealt with in plaintiff's original Pre-Hearing Brief of July 7, 1970, filed more than five months ago. Plaintiff has completely lost sight of the fact that it, not defendant ICI, is the proponent for the relief sought in this case and must therefore bear the burden of showing:

(a) That injunctive relief *of any kind* is necessary (to

[1] ICI did not receive copies of plaintiff's four subpoenas of December 1 and December 4, 1970 until December 10, 1970.

which the third of the factual issues noted above is relevant);

(b) That compulsory sales relief *of any kind* is legally justified (concerning which its Reply Brief adds nothing); and

(c) That compulsory sales; relief *of the peculiar kind* requested by plaintiff is justified (to which presumably the first and second points noted above relate).[2]

In the light of plaintiff's burden, defendant ICI is completely unable to understand under what concept of orderly procedure and fairness to the parties, plaintiff, with almost three years opportunity for discovery (comprehensively utilized by it), should at this late date be engaged in last minute discovery procedure and the further accumulation of affidavits with respect to issues broached earlier in the litigation. Counsel can only deplore the intolerable burden on the defendants imposed by plaintiff's belated spurt of activity.

Even with respect to the three factual issues raised by plaintiff on October 12, defendant ICI has had no time to develop any new evidence; its evidence must needs be limited to documents in the possession of counsel for ICI (including those elicited pursuant to plaintiff's subpoenas).[3] Despite the tactical disadvantage at which plaintiff has placed it, ICI proposes to show that, even on the evidence elicited by plaintiff's last-minute discovery, plaintiff has failed to establish the three propositions orally communicated to counsel on December 12 and has failed to carry its burden of proof.

1.

Defendant ICI deals with a point which plaintiff originally sought to establish but has since abandoned, with re-

[2] If the Court finds that plaintiff has not made out a case under (a), it does not need to reach (b) and (c); similarly if plaintiff has not made out a case under (b), the Court need not reach the issue raised by (c). Hence, plaintiff's first and second factual contentions are of secondary significance.

[3] Time does not permit the verification of documents or matters either by Ayerst in New York City or by ICI in Macclesfield, Cheshire, England. Accordingly, in view of the time stringency posed by plaintiff's belated filing, these matters will be verified by counsel, with the offer to submit subsequent verification by Ayerst or ICI should this prove necessary.

spect to the diminishing nature of the U. S. griseofulvin market. In its December 4 subpoena, plaintiff sought to obtain from Ayerst the market survey data underlying Ayerst's statement in Paragraph 8 of its Affidavit, to the effect that the estimated total U. S. dollar sales of griseofulvin of all manufacturers made to drug stores and hospitals in the United States (including Federal Government contracts) dropped from $7,985,000 in 1967 to $7,081,000 in 1968 and to $6,712,000 in 1969.

The point may have been abandoned by plaintiff, but defendant ICI considers it of considerable significance in this relief proceeding, because the nature of the griseofulvin market is one of the reasons why the bulk resale restriction had no adverse competitive or market effect and was advanced by ICI in support of its position that injunctive relief is not called for in this case (see pp. 9-10 of the defendant ICI's December 3, 1970 Prehearing Brief). Accordingly, ICI proposes to make a matter of record the relevant pages of the market survey (obtained by plaintiff in response to its December 4 subpoena), which was conducted by Davee, Koehnlein & Keating Company, an independent market survey organization particularly eminent as a specialist in the pharmaceutical audit field, see Exhibit 1 appended hereto.

The size and nature of the griseofulvin market is not exactly a new issue in this case. Depositions and interrogatories conducted by plaintiff in the early stages of this litigation had established the small size and competitive nature of the griseofulvin market as the basic reason why other drug firms (Allergan Pharmaceuticals and Abbott) were not willing to enter it. It is suggested that plaintiff could have been more helpful to the Court if it had devoted more time and thought to the size and competitive nature of the U. S. griseofulvin market with which this case is concerned, instead of repeating its pious adjurations to "pry open the market to competition."

2.

Plaintiff contends that Ayerst is in the bulk sales business and purports to support this contention by reference to bulk drug sales figures submitted by American Home Prod-

ucts Corporation (AHPC),[4] in response to its subpoena of December 4, 1970.

However, plaintiff makes no reference at all to AHPC's response to Paragraph II-3 of that subpoena, in which it stated that no documents were found in its files responsive to Paragraph II-3, calling for:—

> "All catalogs of pharmaceutical products offered by Respondent [AHPC] for sale in Bulk Form, distributed since January 1, 1960."

Clearly, no drug firm the size of Ayerst, carrying a large line of products, could be *in the business* of selling pharmaceutical products in bulk without having a catalog covering those products.

Here also, plaintiff's contention is no stranger to this litigation. Depositions taken by the Government from officials of Ayerst, Schering and Johnson & Johnson as far back as April and May, 1968, established that none of these companies were in the business of selling bulk drugs.[5] As far as griseofulvin specifically is concerned, ICI, as long ago as November 29, 1968, stated that it "had received no approaches from any U.S. company for supplying the bulk form griseofulvin for the commercial U.S. griseofulvin market" (see Paragraph 14 of the Bland 1970 Affidavit, appended to defendant ICI's December 3, 1970 Pre-Hearing Brief as Appendix A). Ayerst has stated in Paragraph 3 of its Affidavit (Appendix B to defendant ICI's Dec. 3, 1970 Pre-Hearing Brief) that it had at no time prior to the cancellation of the bulk resale clause in 1967 "even received any inquiries or requests from any company for commercial supplies of bulk griseofulvin for use in the United States."

Even a casual glance at AHPC's bulk drug sale figures

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[4] The Government's subpoenas were served on American Home Products Corporation (AHPC), the parent company of Ayerst. AHPC has another drug subsidiary, Wyeth Laboratories, which was not mentioned in the Government's complaint and has not figured in these proceedings.

[5] Ayerst has defined its business as that "of making and distributing pharmaceutical products to the medical and pharmaceutical professions in final dosage form for administering to patients on a physician's prescription" (see Paragraph 2 of Ayerst Affidavit, App. B to defendant ICI's Dec. 3, 1970 Pre-Hearing Brief).

indicate that Ayerst's bulk drug sales are miniscule, and do not reflect any general company practice or policy of selling drugs in bulk. AHPC's 1969 annual U. S. and foreign sales of drug products can be put at approximately $430,000,000, see Standard & Poor's N.Y.S.E. Stock Reports, Vol. 37, No. 225, Nov. 24, 1970. Ayerst's 1969 dosage sales of griseofulvin alone were $1,596,000, see Paragraph 8 of Ayerst Affidavit. By way of contrast AMHO's total bulk sales for 1969 were slightly over $8,000; total bulk drug sales for the years 1967 and 1968 are in the same eyedropper range.[6] Plaintiff's perception of market realities and statistical acumen must be weak indeed for it to believe that these figures substantiate the proposition that Ayerst is *in the business* of selling bulk drug products.

3.

The point on which plaintiff has lavished most of its prodigious energies is that Ayerst's quoted bulk griseofulvin prices are not commercially viable. One of the main issues posed is that these prices do not permit the generic houses to obtain the proportion of the griseofulvin market which they and the plaintiff think they ought to have. With plaintiff's elaborate coverage of this matter in its July 7, 1970 papers, it is difficult to see what is being served by the massive documentation currently submitted to the Court.

Some slight clarification is achieved by plaintiff's current filing. If one looks at the diagram on page 10A of plaintiff's Reply Brief (see also p. 12A), it becomes clear that Biocraft's thesis (endorsed by plaintiff) is that this Court should decree an industry selling and price structure that would enable *two middlemen*, Biocraft and its distributor, to make a profit, and at the same time enable Biocraft's distributor to sell griseofulvin capsules to the retail druggist at a price 33⅓% below the price quoted the

[6] During the earlier years covered by AMHO's figures, there were somewhat larger sales volumes involved, but this was due to the sale of penicillin (some of it for animal feed purposes), a product not marketed by Ayerst but by Wyeth, another AHPC subsidiary (see page 5, fn. 4). Hence, these volumes are not relevant to plaintiff's contention that Ayerst is in the bulk drug sale business. Even if these penicillin figures were relevant, it is clear that AMHO's total sales of bulk products, even for the year in which its bulk sales loomed highest (1962), were only an infinitismal part of AMHO's pharmaceutical sales in the United States.

druggist by Ayerst or by Ayerst's wholesaler. According to Biocraft, if bulk griseofulvin were made available to it by ICI at the same price at which ICI supplies Ayerst, its "former estimate of capturing a 10% market share was extremely conservative," see p. 5 of second Biocraft Affidavit of December 14, 1970. Biocraft's request for this extraordinary relief is concurred in by another energetic affiant, Owen Laboratories, which assures the Court that, given such relief and its own energy and resources, "it could rapidly achieve 10-20% penetration into the griseofulvin market," see Paragraph 8 of Owen Affidavit, dated December 14, 1970.

The irony of this situation is heightened when it is borne in mind that Ayerst's market share was 16.5% in 1967, 16.0% in 1968 and 23.7% in 1969 (see Paragraph 8 of its Affidavit), less than the putative market share that would accrue to these two energetic affiants. One cannot conceive of a situation more at odds with the competitive system to which the antitrust laws are devoted, and to the functioning of the courts in our legal system, than for this Court to issue a decree guaranteeing to middlemen in the posture of the generic houses and their distributors supplies of griseofulvin at guaranteed low prices with guaranteed profit margins, for the purpose of enabling the distributors to undersell their competitor (Ayerst or Ayerst's wholesaler) by a 33⅓% margin.

Ayerst has been performing processing, handling and marketing services which, as already noted, far transcend in significance the limited functions performed by the generic houses (see pp. 18-19 of defendant ICI's December 3, 1970 brief). There is nothing in the nature of this case to suggest not only that Ayerst (a non-defendant) should lose its exclusive distribution role which it has been performing for ICI in consideration of these services, but that it be put to such a heavy competitive disadvantage vis-à-vis the generic houses. To suggest, as is done in the last sentence of the Biocraft Affidavit, that the Government's request for compulsory sale relief against ICI puts the generic houses "on a fair, equal, and non-discriminatory basis" is meaningless legal verbiage having no connection with business reality or economic common sense.

It is significant that plaintiff's brief makes no mention of Ayerst's reply to its December 4 subpoena requesting

Ayerst to indicate the items recognized by it in quoting prices on bulk griseofulvin. Ayerst's reply stated that its direct factory cost plus royalties accounted for 78% of the $117.00 per kilo price it has quoted for bulk griseofulvin, giving a gross margin of 22% of the quoted price.[7] From the Biocraft affidavits, it appears that a gross margin factor of 40% is considered a "required" return for Biocraft, see pages 22-23 of ICI's Dec. 3, 1970 Pre-Hearing Brief. Biocraft nevertheless says Ayerst's price is too high. In short, the Government's prayer for compulsory sales relief against ICI is a prayer for a bigger margin for Biocraft than Ayerst already has shown a willingness to accept in quoting bulk prices.

With further respect to the viability of Ayerst's bulk prices, Ayerst has forwarded to the plaintiff, in response to the latter's December 4, 1970 subpoena, copies of all correspondence received by it from, and interoffice communications involving, eight companies to which Ayerst quoted bulk microsize griseofulvin prices. One of these firms, Chromalloy American, in a letter to ICI, had indicated that the "pricing on the bulk would be satisfactory," see Exhibit 2 hereto.[8] Two other firms, West-Ward and Sandoz-Wander, have placed orders for bulk microsize for experimental purposes, without raising any question with Ayerst concerning the price quoted them (see Exhs. 8 to 13, inclusive). Another company, SEMED Pharmaceuticals (a division of Massengill), although quoted bulk microsize prices, requested quotations on microsize in capsule form,[9] once again without questioning Ayerst's quotations (see Exhs. 14 and 15). Not a single one of the eight companies involved ever told Ayerst that it considered the bulk price quoted by it to be too high.

It is submitted that even a single statement by a business-

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[7] The verified statement containing this information is the last document attached to plaintiff's Reply Brief.

[8] Chromalloy American originally claimed that the dosage (not the bulk) griseofulvin price was too high, but ended up by expressing an interest in placing an order for microsize griseofulvin in capsules, see Exhs. 5, 6 and 7 hereto.

[9] Paragraph 7 of the Ayerst Affidavit indicates why a prospective buyer may prefer not to purchase in bulk form when he has the alternative of obtaining supplies from Ayerst in an approved dosage form. Thus, Henry Schein, Inc., has requested only microsize capsules (see Exhs. 16 to 19, inclusive).

man, in the course of his normal dealings with other businessmen (such as Chromalloy's statement that the bulk price would be satisfactory), is more genuine and probative than any number of sworn statements made by businessmen in the knowledge that those statements will be used in litigation in an effort to confer a commercial bonanza on them. Plaintiff has failed to make out its case that Ayerst's quoted bulk prices are not commercially viable.

Another curious matter emerging from plaintiff's current filing is the apparent equanimity with which plaintiff regards the prospect of this Court functioning as a rationing agency with respect to the furnishing of bulk griseofulvin by a defendant located in the United Kingdom, confronted with demands for this product emanating from a hundred different countries (see p. 15 of plaintiff's Reply Brief; Paragraph 4 of Bland 1970 Affidavit). Defendant ICI does not share this equanimity.

Plaintiff's Reply Brief also makes the appalling request (see p. 2, fn. 2) that the proceedings be kept open for the purpose of enabling plaintiff to file further affidavits, with respect to factual issues on which it has already inundated the Court with eight industry affidavits and a large number of other documents and with respect to a proposed claim for relief which is legally untenable. It is suggested that this Court has enough self-service business statements before it and that the plaintiff's request not be granted.

Respectfully submitted,

SIGMUND TIMBERG
Attorney for Defendant
Imperial Chemical Industries Limited
815 Fifteenth Street, N. W.
Washington, D. C. 20005

Date: December 16, 1970

AFFIDAVIT OF SIGMUND TIMBERG CONCERNING DOCUMENTS, DATED DEC. 17, 1970

[Caption Omitted]

SIGMUND TIMBERG, being duly sworn, deposes and says:

1. As attorney for defendant Imperial Chemical Industries, I requested Samuel W. Murphy, Jr. Esq., counsel for American Home Products Corporation, to furnish me with copies of the documents supplied by him to plaintiff in response to plaintiff's subpoenas of December 1 and 4, 1970, served upon said corporation. Exhibits 1 and 4 to 19, appended hereto, were among the documents forwarded to me by Mr. Murphy in response to this request.

2. Exhibits 2 and 3, appended hereto, have been forwarded to me by Mr. T. W. M. Bland, Secretary of defendant ICI's Pharmaceutical Division, in the course of my conduct of this litigation.

EXHIBIT 2

CHROMALLOY AMERICAN CORPORATION

June 17, 1970

Mr. T. W. Bland
Imperial Chemical Industries, Ltd.
Pharmaceuticals Division
Alderley House, Alderley Park
Macclesfield, Cheshire,
England

Dear Mr. Bland:

Now that the licensing agreement for griseofulvin between Imperial Chemical Industries and Chromalloy American Corporation has been completed we look forward to the development of a continuing and mutually beneficial business relationship.

At this time I would like to pursue the matter initiated in my letter of January 12, 1970, namely, so that we will be able to perform under the license it will be necessary to cite an NDA master file.

You have informed us on February 9, 1970, that Ayerst Laboratories have been appointed sole importers and distributors of your griseofulvin and that you are not in a position to supply us direct.

On March 23, 1970, Mr. William L. Davis, Executive Vice President of Ayerst after quite some delay quoted us as follows:

250 mg. potency capsules 1,000's $46.60
packaging to be by Chromalloy American Corp.
Bulk griseofulvin—250 kg. quantities $135/kg.

These quotations refer to the microsize form. Mr. Davis further informed us that we would be able to cite the Ayerst NDA on the capsules but not on bulk material.

Our divisions have evaluated the prices furnished by Ayerst and conclude at these pricing levels marketing of griseofulvin in the U. S. is not economically feasible. They cite the fact that Wolins—a generic mail order house—have priced the 250 mg. capsules in 100's to the trade at

$10.00 and that Ayerst's pricing is comparable. A simple arithmetic calculation on the capsules—for which we would have the protection of an NDA—shows the quoted price to be too high.

The pricing on the bulk would be satisfactory if we had NDA protection, but obviously without the right to use the NDA we cannot market the bulk material even though you have granted us a license.

We do not believe it to be the intent of Imperial Chemical Industries to offer a license on griseofulvin and then cite an agreement with a third party which renders the license absolutely valueless.

We have noted that the U.S. Government is investigating the Sherman anti-trust status of the Imperial Chemical Industries/Glaxo Licensing Agreement. While we are not at all familiar with the litigation and naturally intend to preserve any rights which may accrue to us as a result thereof, it seems to us that the existence of the litigation should be sufficient reason for I.C.I. to make both the product and the NDA available to its licensees on competitive terms.

Accordingly, we have reluctantly concluded that the license does not usefully permit us to enter the market, and therefore has no value, unless two conditions are facilitated by your efforts:

(a) Chromalloy American Corporation is supplied with griseofulvin microsize material at competitive prices.

(b) Under conditions which provide us the right to cite all relevant NDA master files.

Please advise us promptly as to the proper course to pursue so that we may market this product.

Yours very truly,
RUSSELL E. LUX

EXHIBIT 3

IMPERIAL CHEMICAL INDUSTRIES LIMITED
PHARMACEUTICALS DIVISION

10th July, 1970.

Mr. Russell E. Lux
Vice President,
Pharmaceutical Group,
Chromalloy American Corporation,
P.O. Box 6303,
Evansville,
Indiana 47712, U.S.A.

Dear Mr. Lux,

GRISEOFULVIN—U.S. PATENT NO. 2,900,304

Thank you for your letter of 17th June. Whilst we are naturally sorry that you are having difficulty in operating under the licence that we have granted you, we are unable to see how we are able to help you.

As indicated in our earlier letter, we are legally bound by our agreement with American Home Products Corporation not to sell in the United States to others than American Home Products. But even if we were legally free to do so we are commercially in no position to act in accordance with your suggestion that we make microsize griseofulvin and the N.D.A. available to you directly.

ICI has never sold microsize griseofulvin into the U.S.A., but only regular grade griseofulvin. Such griseofulvin as ICI produces in the U.K. is of a different grade and quality from that processed from ICI's regular grade bulk griseofulvin and marketed by Ayerst in the U.S.A. ICI has no N.D.A. bearing on griseofulvin.

We have been advised that under American law it would be unlawful for us to attempt to influence the manner in which or price at which Ayerst resells the bulk griseofulvin sold to it; nor can we instruct them to give you the rights to cite relevant N.D.A. master files, although we should certainly have no objection to their doing so.

We can only suggest that you clarify the situation both

with F.D.A. and with Ayerst to see whether there are legal considerations which may bear on the propriety or advisability of Ayerst's N.D.A. being used to cover your manufacturing process in converting the bulk griseofulvin to capsule form.

While we can exercise no control over Ayerst prices we cannot agree with your statement that our licence agreement with you is valueless because the price quoted for capsule form griseofulvin is too high (from your letter it appears that the price quoted on the bulk form of the material is satisfactory). Our information is that at least two ICI licensees have been able to resell commercially griseofulvin bought by them from Ayerst in capsule form. We see no point in our discussing the reasonableness of Ayerst prices since this is necessarily a subjective matter on which judgments may differ. However, the existence of these purchasers of capsule form griseofulvin suggests to us that there is a reasonable relationship between Ayerst bulk and capsule form price quotations.

Yours sincerely,
T. W. M. Bland,
Division Secretary.

Copies to: Dr. J. A. Hendry
Mr. G. H. Hockney
ICI North American Dept.
Mr. J. S. Copp, ICI Legal Dept.
ICI America Inc.
Mr. S. Timberg

EXHIBIT 4

July 17, 1970

Dr. Russell E. Lux
Vice President
Chromalloy American Corporation
P. O. Box 6303
Evansville, Indiana 47712

Dear Dr. Lux:

It has been brought to my attention that some confusion exists as to the possibility of your referring to our NDA on griseofulvin (microsize) in bulk or finished dosage form should you wish to purchase this product from us. The terms and conditions of such purchase are as set forth in Mr. William Davis' letter to you of March 23, 1970. I am writing to you, therefore, to clarify our position.

Should you desire to purchase griseofulvin (microsize) in bulk quantities, this material would be certified in accordance with FDA regulations and in addition we would authorize Chromalloy American to refer to the Ayerst NDA for the manufacturing directions and processes used in the production of the bulk material. This information, which would extend only to production of the bulk, would not be disclosed to you, but as I have indicated, you would be able to refer to it in your NDA submission. Since you would be manufacturing the final dosage form, you would be responsible for satisfying the NDA's requirement on establishing the safety and efficacy of such dosage form.

If, on the other hand, your purchase is of 125 mg. or 250 mg. capsules, we would authorize you to refer to our NDA for manufacturing directions and the safety and efficacy of such dosage form.

I trust this satisfactorily clarifies any questions which you may have and we look forward to hearing from you.

Sincerely,
MAURICE E. SILVERSTEIN

cc: D. Junker

EXHIBIT 5

CHROMALLOY AMERICAN CORPORATION
P.O. BOX 6303 EVANSVILLE, INDIANA 47712

August 18, 1970

Mr. Maurice E. Silverstein, VP
Ayerst Laboratories,
685 Third Ave.,
New York, N.Y. 10017

Dear Mr. Silverstein:

Our Mr. George McConnell, Executive Vice President, Burns Pharmaceuticals will be contacting you regarding proceeding toward the marketing of Griseofulvin 125 and 250 capsules under the Burns label.

We look forward to establishing a useful and profitable business relationship.

Yours truly,
RUSSELL E. LUX

cc: George McConnell

EXHIBIT 6

BURNS PHARMACEUTICALS, INC.

September 8, 1970

Mr. Maurice E. Silverstein, Vice President
Ayerst Laboratories
685 Third Avenue
New York, N. Y. 10017

Dear Mr. Silverstein:

Please refer to Dr. Russell E. Lux's letter to you dated August 18, 1970 regarding our interest in marketing the 125 mg. and 250 mg. capsules of your microsize Griseofulvin.

Dr. Lux advised us you do not have the 500 mg. capsules in microsize only in the regular size, however to offer a complete package we would like to have the 500 mg in the microsize.

We are interested in placing an order for the 125 mg and the 250 mg capsules in bulk for veterinary use based upon the prices quoted to us by Mr. Davis in his letter of March 23, 1970. Would you please confirm these prices. Also *please advise the size* of the *gelatin* capsule for each strength as this is important when you try and "pill" a dog.

We understand from Dr. Lux that Ayerst will file a supplemental New Drug Application with the Food and Drug Administration, therefore would you please *send us copy for the vial labels as* well as the package insert.

We realize before we could market the 125 mg and the 250 mg Griseofulvin Capsules we would have to submit to you twelve copies of our printed vial labels and package inserts for your submission to the FDA.

We propose to use a trade name which we will submit to you when we forward the labeling.

We look forward to hearing from you and thank you for your cooperation.

Very truly yours,
BURNS PHARMACEUTICALS, INC.
GEORGE C. MCCONNELL
Executive Vice President

EXHIBIT 7

September 24, 1970

Mr. George C. McConnell
Executive Vice President
Burns Pharmaceuticals, Inc.
7711 Oakport Street
Oakland, California 94621

Dear Mr. McConnell:

I have your letter of September 8th requesting further information on griseofulvin (microsize) capsules in bulk for veterinary use in 125 mg. and 250 mg. potency. In reviewing this matter further, I have discovered that Ayerst does not sell 250 mg. griseofulvin (microsize) for veterinary use and indeed does not hold an approved NDA for this potency for veterinary use. Our package insert and label for the 125 mg. potency are, however, enclosed. I am also advised that the size of the gelatin capsule for the 125 mg. strength is "Size 1."

As we have previously advised you, our price for 125 mg. potency is $25.15 per 1,000 capsules f.o.b. our plant Rouses Point, New York, net 10 days following the date of invoice. The minimum quantity order is 500,000 capsules. All orders, which should be addressed to us, must be submitted at least three months prior to date of requested delivery.

As explained to Dr. Lux in my letter to him of July 17, 1970, purchasers of dosage form griseofulvin from Ayerst would be authorized to refer to our NDA for manufacturing directions and safety and efficacy of such dosage form.

I look forward to hearing from you.

Very truly yours,
MAURICE E. SILVERSTEIN

cc: W. L. Davis
D. Junker

EXHIBIT 8

AYERST NYC

AYERST ROUPT

WX 23 8/10/70 9:00

NEW YORK

AHPC—LAW DEPARTMENT

MR. MAURICE SILVERSTEIN

ONE KG. GRISEOFULVIN MICROSIZE SHIPPED TO WEST-WARD INC. AUGUST 6, 1970.

F. R. FORBES

LA

EXHIBIT 9

July 27, 1970

Dear Frank:

Enclosed is a purchase order we have received from West-Ward, Inc. requesting one (1) kilogram of griseofulvin microsize for testing purposes.

We are most willing to comply with this purchase order and I would be grateful if you would see to it that the one kilo is shipped out properly labeled at your earliest convenience. Perhaps it would be in order for you to check with Howard Cmejla to be sure that all the regulatory aspects are taken care of.

You may notice that the purchase order reads "F.O.B. our plant," but nevertheless we have quoted West-Ward, Inc. on the basis of F.O.B. Rouses Point and I would ask that you bill them on this basis.

Would you kindly let me know when the one (1) kilo has been shipped.

Sincerely,

cc: Dr. H. R. Cmejla
R. Marra

[redacted]

PURCHASE ORDER Exhibit 10

Westward, Inc. № 2359

745 Eagle Avenue
Bronx, N. Y. 10456

[redacted]

Averst Laboratories
Division of American Home Products Corp.
685 Third Avenue
New York, New York 10017

Date July 21, 1970

Shipping Instructions
F.O.B. Our Plant

Att: Mr. Maurice E. Silverstein

[redacted]

Kindly enter our order for the following:

QUANTITY	DESCRIPTION	UNIT PRICE	AMOUNT
1 Kilogram	Griseofulvin (Microsize) Powder U.S.P.		$141.00

Please supply an assay report

By Edw. Green
Edward Green

Items which are affected by the Federal Food and Drugs or the Insecticide Acts must comply in the strictest sense with these laws and amendments thereto and the invoice for such goods must bear the guarantee that the goods comply with these acts as amended and signature and address of guarantor.

EXHIBIT 11

CONFIRMATION FROM SANDOZ-WANDER

October 28, 1970

cc: W. L. Davis
J. G. Faherty
D. Junker

Dear Frank:

Attached is a corrected purchase order from Sandoz-Wander Inc. requesting one kilo of griseofulvin (micro-size) at the price of $141.00.

As I previously indicated in my memo of October 15th on this matter, would you kindly process this order providing of course that the raw material is available.

Best regards,

Sincerely,

Exhibit 12

SANDOZ - WANDER INC.

DATE: 10/16/70

38404 KR

ROUTE 10 P.O. BOX 13
HANOVER, NEW JERSEY 07936

TELEPHONES: (201) 386-7611, 7612, 7613, 7614, 7615, 7616

CHECK (✓) IF THIS IS CONFIRMATION OF TELEPHONE CALL

SHOW OUR ORDER NUMBER ON ALL INVOICES, DELIVERY RECEIPTS & PACKAGES. SUPPLIER'S LOT OR BATCH NUMBER MUST APPEAR ON ALL CONTAINERS OF CHEMICALS. DO NOT DELIVER AFTER 4 P.M. OR ON SATURDAYS.

VENDOR NAME	TERMS	F.O.B.
Ayerst Laboratories Inc.	2% 45	Delivered
STREET ADDRESS	SHIP TO:	
685 Third Avenue		
CITY & STATE — ZIP CODE	DATE REQUIRED	VENDOR #
New York, New York 10017, Attn: M. Silverstein	11/15/70	

REQUISITIONING DEPARTMENT -- COMPLETE INFORMATION IN HEAVY OUTLINED AREA BELOW -- TYPE OR PRINT

SUGGESTED SUPPLIER AND ADDRESS

REQUISITION DATE	DATE WANTED	BLDG., NO. & DEPT.	COST UNIT (30-33)	CHG. NO. OR CAPITAL EXPEND. ITEM #
		Bldg. 410 Lab 311 (Herklinger)	44-15	

MATERIAL NO. (12-20)	QUANTITY ORDERED (21-26)	DESCRIPTION (GIVE SPECIFICATION NUMBERS IF ANY)	PACKAGE (27-29)	UNIT COST	AMOUNT (30-38)
	1 kg	Griseofulvin Micro	kg		141.00

CONFIRMATION

REQUISITIONED: APPROVED BY: BUYER

RECEIVING DEPARTMENT

DATE RECEIVED	TIME RECEIVED	CARRIER	FREIGHT BILL NO.	FREIGHT PAID

PPD. COLLECT CHARGES	PART.	COMP.	REMARKS	RECEIVED BY

INSTRUCTIONS

ALL GOODS MUST BE SIGNED FOR IMMEDIATELY UPON DELIVERY TO A DEPARTMENT. IF INVOICE SHOULD BE HELD FOR PAYMENT PENDING PARTIAL SHIPMENT, RECEIVING REPORT.

DISPOSITION OF MERCHANDISE

DEPT.	SIGNATURE	DATE	
DEPT.	SIGNATURE	DATE	DRIVER'S NAME

VENDOR

EXHIBIT 13

October 15, 1970

Dear Frank:

We have received a request for one kilo of griseofulvin (microsize) from Sandoz Pharmaceuticals, Route #10, Hanover, New Jersey. Provided this does not interfere with your regular requirements, I would appreciate your honoring this request at your convenience and billing Sandoz at the price of $141.00. The material should be sent to Sandoz at the aforementioned address, Building #404, Order No. 38404KR.

With best regards,

Sincerely,

P.S. As usual the material should be sent F.O.B. Rouses Point, New York.

cc: W. L. Davis
D. Junker
J. G. Faherty

EXHIBIT 14

THE S. E. MASSENGILL COMPANY

BRISTOL, TENNESSEE 37620

December 4, 1970

Mr. Maurice E. Silverstein
Vice President
Ayerst Laboratories
Division of American Home Products Corp.
685 Third Avenue
New York, N. Y. 10017

Dear Mr. Silverstein:

In re Griseofulvin.

This is in reply to your letter of October 13, 1970 to Mr. John Calderbank relative to griseofulvin. We continue to have an interest in the possibility of marketing this product for veterinary use.

In your October 13 letter you quote prices for finished capsules and also for bulk griseofulvin (microsize). Is there a possibility that you would be interested in also packaging the capsules for us, i.e., Ayerst would do the complete packaging and labeling with labels to be supplied by Massengill? We would appreciate a quotation on the finished package if such is possible.

Yours very truly,
WILBUR R. JONES
Vice President, Technical Affairs

cc: Mr. John G. Calderbank

EXHIBIT 15

October 13, 1970

SEMED Pharmaceuticals
Division of the S. W. Massengill Co.
Bristol, Tenn. 37620
Attention: John G. Calderbank, Marketing Director

Dear Mr. Calderbank:

Your letter of September 24th suggesting a possible licensing agreement for acepromazine and griseofulvin (microsize) for veterinary use has been referred to me for reply.

I should tell you that our present plans do not include entering into the type of arrangement which you suggest for acepromazine. We are, however, making griseofulvin (microsize) available to third parties subject to the terms and conditions set forth below. You should know, however, that at the present time we have a New Drug Application covering griseofulvin (microsize) for veterinary use for the 125 mg. potency only.

Our price for the 125 mg. potency is $25.15 per 1,000 capsules. Minimum quantity order is 500,000 capsules. The capsules will be supplied to you for packaging by you and the color of the capsules will be as specified by you provided such color is not the same as, or confusingly similar to that used by Ayerst. Terms for the above are f.o.b. our plant Rouses Point, New York, net 10 days following date of invoice. All orders should be addressed to me and must be submitted at least three months prior to date of requested delivery.

I must further emphasize that because our ability to supply you is contingent upon the availability of raw material from our supplier, all prices quoted to you are subject to change or withdrawal at any time without prejudice to us.

[Illegible]

We are also able to supply to you griseofulvin (microsize) in bulk at the following prices:

Quantity	Price
25- 99 kilograms per shipment	$141 per kilogram
100-249 kilograms per shipment	$138 per kilogram
250 kilograms and over per shipment	$135 per kilogram

Minimum order—25 kilograms

Bulk material would be supplied to you at the same terms and conditions set forth above except that if you should desire to buy bulk material you would be authorized to refer to Ayerst's NDA for manufacturing directions, but you would, of course, have to establish the safety and efficacy of the finished dosage form to satisfy the FDA's requirements.

I look forward to hearing from you.

Very truly yours,

MAURICE E. SILVERSTEIN

cc D. Junker
S. Lindsay
W. L. Davis
J. G. Faherty

EXHIBIT 16

October 28, 1970

Henry Schein Inc.
39-01 170th Street
Flushing, New York 11358
Attention: Martin Sperber

Dear Mr. Sperber:

I am reluctantly returning to you your purchase order #36478 covering your order for 500,000 capsules griseofulvin (microsize) 250 mg. at $46.30 per 1,000. As I mentioned to you on the telephone, I believe it would be unnecessarily confusing if we were to supply you with capsules of the same color as that supplied to another customer, Zenith Laboratories, without the consent of Zenith. As you know, we insist that the color capsules you select be different and not confusingly similar to that used by Ayerst and we believe our customers are entitled to the same consideration.

If you would, therefore, select a different color, we would be pleased to process your order under the same terms and conditions as set forth in our previous correspondence.

Very truly yours,

MAURICE E. SILVERSTEIN

cc D. Junker

EXHIBIT 17

HENRY SCHEIN, INC.
39-01 170th Street
Flushing, New York 11358

October 19, 1970

Ayerst Labs
685 Third Ave.
New York, N. Y. 10017

Att: Mr. Maurice E. Silverstein

Dear Mr. Silverstein:

As per our telephone conversation, I have sent you under separate cover a sample of the Griseofulvin Tablets which we are presently marketing.

Enclosed is our purchase order for 500,000 capsules, 250 mg. to be forwarded to Danbury Pharmacal Co. These will be packaged by Danbury under our label and possibly another label.

Would you please forward to them, attention of Mr. Ira Sachs, the necessary papers and information which will allow them to package this material in compliance with Food and Drug regulations.

If you have any further questions, please contact me.

Sincerely,

MARTIN SPERBER

Exhibit 14

LE 9-4850 PURCHASE ORDER

THIS NUMBER AND DATE MUST APPEAR ON ALL INVOICES, PACKAGES, SHIPPING PAPERS AND CORRESPONDENCE.

HENRY Schein INC.

WHOLESALE OF PHARMACEUTICAL, SURGICAL AND DENTAL SUPPLIES
39-01 170TH STREET, FLUSHING, NEW YORK 11358
F.D.A. REG. # 30-1128

No. 36478

10/16/70

SHIP TO HENRY SCHEIN UNLESS OTHERWISE SHOWN BELOW

SUGGEST

Ayerst Labs -

Danbury Pharmacal
131 West ST
Danbury, Conn.

Attn: Mr. Maurice Silverstein

PLEASE ENTER OUR ORDER FOR THE FOLLOWING SUBJECT TO TERMS AND CONDITIONS HEREON

SHIP VIA FOB Rouses Point - 90 Days TERMS Net 10 Days

QUANTITY	SIZE	DESCRIPTION
500,000		capsules Griseofulvin 250mg (microsize) 46.30/1000
(Nitrofurantoin Capsule Sample sent seperately)		
		You will forward to Danbury all papers necessary for them to package this material in compliance with Food-Drug Regulations

IF THIS ORDER CANNOT BE SHIPPED WITHIN 120 DAYS, WE MUST BE NOTIFIED IMMEDIATELY.

M Sherlen

THE SELLER BY ACCEPTING THIS PURCHASE ORDER DOES HEREBY GUARANTEE THAT NO ARTICLE LISTED HEREIN TO BE SOLD TO THE PURCHASER IS OR SHALL BE ADULTERATED OR MISBRANDED WITHIN THE MEANING OF THE FEDERAL FOOD DRUG AND COSMETIC ACT, AT THE TIME OF DELIVERY IS OR IS OR SHALL BE AN ARTICLE WHICH MAY NOT, UNDER THE PROVISIONS OF SECTION 404 OR 505 OF THE SAID ACT BE INTRODUCED INTO INTERSTATE COMMERCE.

EXHIBIT 19

September 3, 1970

Mr. Martin Sperber
Henry Schein Inc.
39-01 170th Street
Flushing, New York 11358

Dear Mr. Sperber:

In response to your letter of May 5, 1970, I am pleased to quote you the following prices on griseofulvin capsules (microsize):

125 mg. potency at $25.15 per 1,000 capsules
250 mg. potency at $46.30 per 1,000 capsules

Prices quoted above are in bulk for packaging by you. Color of capsules will be as specified by you provided such colors are not the same as, or confusingly similar to that used by Ayerst.

Furthermore, all prices quoted herein are F.O.B. our plant Rouses Point, New York and [Illegible]

I must emphasize that because our ability to supply you is contingent upon the availability of raw material from our supplier, all prices quoted herein are subject to withdrawal at any time without prejudice to us. Finally we [Illegible]

I look forward to hearing from you.

Sincerely,

MAURICE E. SILVERSTEIN

VERIFIED STATEMENT OF MAURICE E. SILVERSTEIN, DATED DEC. 11, 1970, CONCERNING COSTS OF AMHO GRISEOFULVIN BUSINESS

[Caption Omitted]

STATEMENT IN RESPONSE TO PARAGRAPH 3 OF SUBPOENA DUCES TECUM, DATED DECEMBER 4, 1970
ADDRESSED TO
AMERICAN HOME PRODUCTS CORPORATION

Recognition has been given by Ayerst Laboratories to factory costs and royalty incurred by it for regular griseofulvin powder, packaged in bulk containers, amounting in the aggregate to approximately 78% of the price of $117.00 per kilo at which this product is offered for sale. These costs include:

Price paid to ICI for material	$77.95	per kilo
Freight, insurance and import duties and charges	$ 2.93	per kilo
Product assays and tests, processing and packing materials and labor	$ 5.08	per kilo
Royalty paid ICI	$ 5.85	per kilo

Other costs and items of expense are not allocated by product on the company's books. Each product sold by the company, however, must assist in bearing the burden of the unallocated costs and expenses incurred in maintaining the facilities and personnel necessary for research and development, maintenance of medical department, administrative and distribution expenses, medical detailing and promotion, general management and other activities incident to an ethical pharmaceutical business.

A factory cost of 78% on bulk regular griseofulvin represents a net return to Ayerst after taxes of approximately 11.4%, from which the company must support the above-noted unallocated costs and earn a necessary profit.

Maurice E. Silverstein, being duly sworn, deposes and says:

That he is Vice-President of Ayerst Laboratories Division of American Home Products Corporation.

That he has read the foregoing statement and that all matters stated therein are true to the best of his knowledge, information and belief.

INTERROGATORIES SERVED BY GOVERNMENT ON JULY 16, 1968 (NOT ANSWERED)—NOS. 2-14, 16-33 *

2. State Defendant's contentions as to the meaning of "effective amount" as used in the claims of the Imperial Patent.

3. State Defendant's contentions as to the effective amount in terms of type of dosage form, amount of dosage, frequency of administration, and duration of administration, for the cure of each disease listed in response to interrogatory 1.

4. List (giving author, title, publisher, date, page, and paragraph number) all textbooks, treatises, and other sources of information, if any, known to Defendant to have been available to the public as of September 3, 1957, which disclose the effective amounts listed in response to interrogatory number 3.

5. List (giving author, title, publisher, date, page, and paragraph number) all textbooks, treatises, and other sources of information, if any, known to Defendant to have been available to the public as of August 18, 1959, which disclose the effective amounts listed in response to interrogatory number 3.

6. (a) State whether Defendant contends that the Imperial patent teaches or discloses what amount constitutes "an effective amount" of Griseofulvin for effectuating cures of external fungus diseases; and

(b) if Defendant so contends, state Defendant's contentions as to how the Imperial patent teaches or discloses what amount constitutes such "an effective amount."

7. State Defendant's contentions as to the earliest dates on which Griseofulvin was

(a) known or used in the United States;

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* Unless otherwise noted Glaxo objected to each interrogatory on Aug. 20, 1968; and, except for 16(a)-(e), ICI objected on Sept. 3, 1968. The objections were sustained by the Pretrial Examiner, Nov. 6, 1968.

(b) patented in the United States or any foreign country;
(c) described in a printed publication in the United States or any foreign country;
(d) in public use in the United States; and/or
(e) on sale in the United States.

8. For each of the dates given in response to Interrogatory 7, describe and identify fully the sale, publication, patent, public use, etc., to which such date relates.

9. (a) State whether Defendant contends that each of the statements in the second paragraph of the specification of United States Patent No. 2,900,304 * is true. (If Defendant contends that some statements are true and some are not true, specify such contentions.)
(b) State the sources of information which Defendant contends form a basis for each statement made in the second paragraph of the specification of United States Patent No. 2,900,304; and
(c) State the sources of information which, Defendant contends, were available to the public as of September 3, 1957, and which in any way corroborate such statements.

10. State the date on which Defendant contends the alleged invention in the Imperial Patent occurred (hereafter referred to as "Imperial Invention Date").

11. State whether Defendant contends Griseofulvin was or was not

(a) known or used by others in the United States, or patented or described in a printed publication in this or a foreign country, before the Imperial Invention Date; or
(b) patented or described in a printed publication in the United States or a foreign country or in public use on or sale in this country, prior to September 21, 1955.

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* Such paragraph reads:

"Griseofulvin is a known antibiotic and it is known to be useful in the treatment of certain fungus diseases of plants. It has not hitherto been used in the treatment of fungus diseases of man and animals."

12. State whether Defendant contends that valid United States patents, other than process patents, can be granted on chemical substances which were—

(a) known or used by others in the United States, or patented or described in a printed publication in this or a foreign country, before the date of the alleged invention; or

(b) patented or described in printed publication in the United States or a foreign country or in public use or on sale in this country, more than one year prior to the effective date of the application for the patent.

13. If the answer to Interrogatory 12 is affirmative, state Defendant's contentions as to the circumstances in which valid United States patents, other than process patents, can be granted on chemical substances which were—

(a) known or used by others in the United States, or patented or described in a printed publication in this or a foreign country, before the date of the alleged invention; or

(b) patented or described in printed publication in the United States or a foreign country or in public use or on sale in this country, more than one year prior to the effective date of the application for the patent.

14. State whether, and if so, how, the facts and circumstances relating to the grant of the Imperial Patent bring it within the scope of the contentions set forth in response to Interrogatory 13.

16. (a) State the Particle Sizes of Regular Size Griseofulvin manufactured and/or supplied by (i) Glaxo and (ii) Imperial for each of the years 1954 through 1968;

(b) State whether each such Particle Size is a mean size, medium size, maximum size, minimum size, predominant size, or whether all particles are of identical Particle Size;

(c) If all particles are not of identical Particle Size, state the minimum and maximum Particle Size and describe the distribution of the other Particle Sizes;

(d) State the means by which such Particle Sizes were determined;
(e) List the names of all persons participating in the determination of such Particle Sizes, and the dates on which such determinations were made;
(f) State the approximate number of Documents which in any way refer to such Particle Sizes;
(g) Give the Document Identity for each Document which in any way refers to such Particle Sizes; and
(h) List all descriptions used in such Documents relating to Particle Sizes.

[Nos. 16(f)-(h) withdrawn by Stipulation dated Aug. 20, 1968.]

17. State the date on which Defendant contends the alleged invention in United States Patent No. 3,330,727 occurred (hereafter referred to as "Microsize Invention Date").

18. State whether Defendant contends any Griseofulvin particle of such size that its specific surface area would be within those specific surface areas claimed in United States Patent No. 3,330,727 was

(a) known or used by others in the United States, or patented or described in a printed publication in this or a foreign country, before the Microsize Invention Date; or
(b) patented or described in a printed publication in the United States or a foreign country or in public use on or sale in this country, prior to April 17, 1960.

19. If the answer to Interrogatory 18 is affirmative, state Defendant's contentions as to the circumstances in which valid United States patents, other than process patents, can be granted on particular particle sizes of chemical substances where such particle sizes of such substance were—

(a) known or used by others in the United States, or patented or described in a printed publication in this or a foreign country, before the date of the alleged invention; or
(b) patented or described in printed publication in the United States or a foreign country or in public

use or on sale in this country, more than one year prior to the effective date of the application for the patent.

20. State whether, and if so, how, the facts and circumstances relating to the grant of United States Patent No. 3,330,727 bring it within the scope of the contentions set forth in response to Interrogatory 19.

21. (a) State Defendant's contentions with respect to whether the claims of United States Pat. No. 3,330,727 would be infringed by the unauthorized manufacture, use, or sale of a single particle of Griseofulvin having the specific surface area set forth in the claims of that patent;

(b) If the response to (a) is negative, state Defendant's contentions as to the number of particles (or relative proportion thereof) having a specific surface area as set forth in the claims of such patent, which would be necessary to so infringe the above-mentioned patent and the manner in which such particles must be associated to so infringe;

(c) Describe fully all methods known to Defendant for measuring specific surface areas of Griseofulvin particles, stating the types of equipment used, modes of operation of such equipment, personnel required, etc.; and

(d) For each method described in (c), indicate whether Defendant contends such method is or is not sufficiently accurate to determine whether the measured particles infringe the claims of United States Patent No. 3,330,727.

22. (a) With reference to United States Pat. No. 2,986,496, col. 4, lines 51-54, state the basis for the statement:

We have, for example, micronized these solids satisfactorily to give particles less than 10 microns with more than 90% of the particles below 5 microns.

(b) Identify by name, address, and job title, all persons participating in such micronization;

(c) State the dates on which such micronization occurred;

(d) State the approximate number of Documents which in any way refer to such micronization;

(e) Give the Document Identity of all Documents which in any way refer to such micronization; and

(f) List all descriptions used in such Documents relating to Particle Sizes.

[Nos. 22(d)-(f) withdrawn by stipulation dated Aug. 20, 1968.]

23. State all reasons which Defendant contends cause the alleged higher efficacy of Microsize Griseofulvin.

24. (a) State Defendant's contentions with respect to whether a dosage unit of Griseofulvin consisting in part of Regular Size and in part of Microsize Griseofulvin would be more effective than a dosage unit of equivalent weight Griseofulvin consisting solely of Regular Size Griseofulvin;

(b) State Defendant's contentions with respect to whether the efficacy of such a mixture of Regular and Microsize Griseofulvin would increase with increased proportions of Microsize Griseofulvin;

(c) If the answer to (b) is yes, state Defendant's contentions with respect to whether the increased efficacy is or is not linearly proportional to the increased Microsize Griseofulvin content;

(d) If such efficacy is contended not to be so linearly proportional, state Defendant's contentions with respect to the manner in which such increased efficacy varies with increased Microsize Griseofulvin content, specifying any allegedly critical points or proportions;

(e) State the approximate number of Documents that support or tend to corroborate the contentions stated in response to the foregoing paragraphs; and

(f) Give the Document Identity of all such Documents.

25. (a) State Defendant's contentions with respect to whether the efficacy of a dosage unit of Griseofulvin increases if the specific surface area of the Griseofulvin in such dosage unit is increased;

(b) If the answer to (a) is yes, state Defendant's

contentions with respect to whether the increased efficacy is or is not linearly proportional to the increased specific surface area;

(c) If such efficacy is contended not to be so linearly proportional, state Defendant's contentions with respect to the manner in which such increased efficacy varies with increased specific surface area, specifying any allegedly critical points or values;

(d) State the approximate number of Documents that support or tend to corroborate the contentions stated in response to the foregoing paragraph; and

(e) Give the Document Identity of all such Documents.

26. (a) State Defendant's contentions with respect to whether the efficacy of Griseofulvin increases with smaller particle size;

(b) If the answer to (a) is yes, state Defendant's contentions with respect to whether the increased efficacy is or is not linearly proportional to particle size;

(c) If such efficacy is contended not to be so linearly proportional to particle size, state Defendant's contentions with respect to the relationship between particle size and increased efficacy, specifying any allegedly critical points or values;

(d) State the approximate number of Documents that support or tend to corroborate the contentions stated in response to the foregoing paragraph; and

(e) Give the Document Identity of all such Documents.

27. (a) State Defendant's contentions with respect to whether a dosage unit of Griseofulvin consisting in part of Regular Size and in part of Microsize Griseofulvin would have a higher absorption rate than a dosage unit of equivalent weight Griseofulvin consisting solely of Regular Size Griseofulvin;

(b) State Defendant's contentions with respect to whether the higher absorption rate of such a mixture of Regular and Microsize Griseofulvin

would increase with increased proportions of Microsize Griseofulvin;

(c) If the answer to (b) is yes, state Defendant's contentions with respect to whether the increased higher absorption rate is or is not linearly proportional to the increased Microsize Griseofulvin content;

(d) If absorption rate is contended not to be so linearly proportional, state Defendant's contentions with respect to the manner in which such higher absorption rate varies with increased Microsize Griseofulvin content, specifying any allegedly critical points or proportions;

(e) State the approximate number of Documents that support or tend to corroborate the contentions stated in response to the foregoing paragraph; and

(f) Give the Document Identity of all such Documents.

28. (a) State Defendant's contentions with respect to whether the absorption rate of a dosage unit of Griseofulvin increases if the specific surface area of the Griseofulvin in such dosage unit is increased;

(b) If the answer to (a) is yes, state Defendant's contentions with respect to whether the increased absorption rate is or is not linearly proportional to the increased specific surface area;

(c) If such absorption rate is contended not to be so linearly proportional, state Defendant's contentions with respect to the manner in which such increased absorption rate varies with increased specific surface area, specifying any allegedly critical points or values;

(d) State the approximate number of Documents that support or tend to corroborate the contentions stated in response to the foregoing paragraph; and

(e) Give the Document Identity of all such Documents.

29. (a) State Defendant's contentions with respect to whether the absorption rate for Griseofulvin increases with smaller particle size;

(b) If the answer to (a) is yes, state Defendant's contentions with respect to whether the increased absorption rate is or is not linearly proportional to particle size;

(c) If such absorption rate is contended not to be so linearly proportional to particle size, state Defendant's contentions with respect to the relationship between particle size and absorption rate, specifying any allegedly critical points or values;

(d) State the approximate number of Documents that support or tend to corroborate the contentions stated in response to the foregoing paragraph; and

(e) Give the Document Identity of all such Documents.

30. (a) State Defendant's contentions with respect to whether a dosage unit of Griseofulvin consisting in part of Regular Size and in part of Microsize Griseofulvin would have a longer blood retention time than a dosage unit of equivalent weight Griseofulvin consisting solely of Regular Size Griseofulvin;

(b) State Defendant's contentions with respect to whether the blood retention time of such a mixture of Regular and Microsize Griseofulvin would increase with increased proportions of Microsize Griseofulvin;

(c) If the answer to (b) is yes, state Defendant's contentions with respect to whether the increased blood retention time is or is not linearly proportional to the increased Microsize Griseofulvin content;

(d) If such blood retention time is contended not to be so linearly proportional, state Defendant's contentions with respect to the manner in which such blood retention time varies with increased Microsize Griseofulvin content, specifying any allegedly critical points or proportions;

(e) State the approximate number of Documents that support or tend to corroborate the contentions stated in response to the foregoing paragraph; and

(f) Give the Document Identity of all such Documents.

31. (a) State Defendant's contentions with respect to whether the blood retention time of a dosage unit of Griseofulvin increases if the specific surface area of the Griseofulvin in such dosage unit is increased;

(b) If the answer to (a) is yes, state Defendant's contentions with respect to whether the increased blood retention time is or is not linearly proportional to the increased specific surface area;

(c) If such blood retention time is contended not to be so linearly proportional, state Defendant's contentions with respect to the manner in which such increased blood retention time varies with increased specific surface area, specifying any allegedly critical points or values;

(d) State the approximate number of documents that support or tend to corroborate the contentions stated in response to the foregoing paragraph; and

(e) Give the Document Identity of all such Documents.

32. (a) State Defendant's contentions with respect to whether the blood retention time for Griseofulvin increases with smaller particle size;

(b) If the answer to (a) is yes, state Defendant's contentions with respect to whether the increased blood retention time is or is not linearly proportional to particle size;

(c) If such blood retention time is not linearly proportional to particle size, state Defendant's contentions with respect to the relationship between particle size and blood retention time, specifying any allegedly critical points or values;

(d) State the approximate number of documents that support or tend to corroborate the contentions stated in response to the foregoing paragraph; and

(e) Give the Document Identity of all such Documents.

33. With reference to the Examples of United States

Patent No. 2,900,304 and the work underlying such Examples, state specifically for each Example:

(a) The type or form (such as liquid suspension, powder size, solid, etc.) of the Griseofulvin used;
(b) The type (manufacturer, model, and approximate date of manufacture) of the ball mill used;
(c) The settings of the controls of such ball mill;
(d) The length of time such ball mill was operated;
(e) The types of attachments used with such ball mill;
(f) The name and present (or last known) address of each person who participated in the work underlying such Examples;
(g) Whether the Particle Size of the Griseofulvin involved was measured;
(h) The stage of the work at which such measurement occurred;
(i) The method or methods used to determine the Griseofulvin Particle Size;
(j) State the approximate number of Documents which in any way relate to the work underlying such Examples;
(k) Give the Document Identity of all Documents which in any way relate to the work underlying such Examples; and
(l) List all descriptions used in such Documents relating to Particle Sizes.

PLAINTIFF'S INTERROGATORIES PROPOUNDED TO DEFENDANT ICI, DATED OCT. 16, 1968 (NOT ANSWERED)*

[Caption Omitted]

Pursuant to Rule 33 of the Federal Rules of Civil Procedure, plaintiff hereby requests defendant Imperial Chemical Industries Ltd., by its duly authorized officers and agents, to answer and serve upon plaintiff sworn answers in writing to the following interrogatories, within fifteen (15) days.

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* Objected to, and objections sustained by Pretrial Examiner on Nov. 15, 1968.

I. DEFINITIONS

1. "Finished Pharmaceutical Form" means the packaged form in which pharmaceutical products are distributed for use by or administration to the ultimate consumer thereof.

2. "Bulk Form" means any form other than finished pharmaceutical form.

3. "Griseofulvin" is the generic name for, and means, the antibiotic compound with the formula 7-chloro-2', 4, 6-trimethoxy-6'-methylspiro [benzofuran-2 (3-H), 1'-[2]-cyclohexane]-3, 4'-dione (empirical formula, C_{17} H_{17} Cl O_6).

4. "Bulk Sale Restriction" means a provision in a license or other agreement which prohibits or fails to authorize the licensee or vendee to sell the licensed product or product sold, products containing the licensed product or product sold or products produced by the licensed process, in Bulk Form. The term includes any such provision, whether in the form of a restraint on alienation, a limited grant to make, use, or sell, or otherwise.

5. "Griseofulvin Distributorship Agreement" means the agreement between Imperial Chemical Industries Ltd. and American Home Products Corporation relating to distribution of Griseofulvin and described as a "distributorship agreement" in Imperial's response to plaintiff's interrogatory number 47 propounded July 16, 1968.

II. INTERROGATORIES

1. State whether Imperial Chemical Industries Ltd. contends that there is or is not, or was or was not, a Bulk Sale Restriction in the Griseofulvin Distributorship Agreement.

2. (a) List every factor, whether business, economic, legal, or otherwise, which Imperial Chemical Industries Ltd. contends is a justification for the Bulk Sale Restriction which is in or was in the Griseofulvin Distributorship Agreement;

(b) For each such justification, state the contentions of Imperial Chemical Industries Ltd. as to the relationship between such Bulk Sale Restriction and each of the allegedly desired or justifiable effects and purposes served by the Bulk Sale Restriction, indicating the manner and extent to which Imperial Chemical Industries Ltd. contends that the former brings about the latter.

STIPULATION DATED AUG. 19, 1968

[Caption Omitted]

It is hereby stipulated between plaintiff and defendant Imperial Chemical Industries Limited that with respect to plaintiff's Rule 34 motion dated July 1, 1968, as follows:

1. Defendant Imperial Chemical Industries Limited will produce the documents and materials specified in the attached Schedule.

2. Plaintiff withdraws its Rule 34 motion directed to Imperial Chemical Industries Limited dated July 1, 1968.

3. This stipulation is entered into without any prejudice to any party with respect to seeking further discovery in this case.

SCHEDULE

I. DEFINITIONS

1. "Respondent" means the corporation to which this pleading is directed; all subsidiaries, parents, corporate affiliates, and divisions of such corporation; any corporate predecessor or successor of any of the foregoing; directors, officers, employees, agents, and attorneys thereof; and any person acting on behalf thereof.

2. "Finished Pharmaceutical Form" means the packaged form in which pharmaceutical products are distributed for use by or administration to the ultimate consumer thereof.

3. "Bulk Form" means any form other than finished pharmaceutical form.

4. "Griseofulvin" is the generic name for, and means, the antibiotic compound with the formula 7-chloro-2′, 4, 6-trimethoxy-6′-methylspiro [benzfuran-2 (3-H), 1′-[2]-cyclohexane]-3, 4′-dione (empirical formula, C_{17} Z_{17} Cl O_6) and/or such formula as respondent contends is a description of Griseofulvin.

5. "Document" includes the original and any nonidentical copy (whether different from the original because of notes made on or attached to such copy or otherwise) of all letters, telegrams, memoranda, reports, and all other documentary material of any nature whatever in the possession, custody, or control of respondent. "Document"

does not include, for the purposes of this pleading, those documents written prior to January 1, 1955.

II. DOCUMENTS AND MATERIALS TO BE PRODUCED

1. All bulk form griseofulvin in the possession, custody, or control of respondent which respondent has reason to believe was manufactured and shipped to the U. S. prior to April 17, 1960 or which respondent has reason to believe is from batches of bulk form griseofulvin, other portions of which were likely to have been shipped to the U. S. prior to April 17, 1960, together with the containers (or a copy of all writing on such containers) in which it is found.

2. All finished pharmaceutical form griseofulvin in the possession, custody, or control of Respondent which Respondent has reason to believe was manufactured and shipped to the U. S. prior to April 17, 1960, which Respondent has reason to believe is from batches of finished pharmaceutical form griseofulvin, other portions of which were likely to have been shipped to the U. S. prior to April 17, 1960, or which Respondent has reason to believe were manufactured from bulk form griseofulvin of the type identified in paragraph II-1 above, together with the containers (or a copy of all writing on such containers) in which it is found.

3. All documents which discuss, refer to, comment on, or in any way relate to (i) the date on which Respondent received, manufactured, or formulated any griseofulvin responding to paragraphs II-1 and/or II-2, and/or (ii) the sizes of the particles and/or surface areas of any griseofulvin responding to paragraphs II-1 and/or II-2.

4. All documents (a) prepared by, for, or received by respondent prior to January 1, 1962, which discuss, comment on, refer to, or in any way relate to the particle size of griseofulvin and/or (b) prepared by or for, or received by Respondent subsequent to January 1, 1962, which discuss, comment on, refer to, or in any way relate to the relationship between the particle size of griseofulvin and its physiological effects (including, but not limited to, absorption rate, blood retention time, and efficacy) and/or methods of measuring the particle size of griseofulvin.

EXCERPT FROM DEPOSITION OF E. J. BROWNING, TAKEN JUNE 24, 1968, FILED SEPT. 13, 1968

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[p. 7] A. No, just to do a better job.

Q. How did you first become aware that your company was looking at the possibility of getting into the Griseofulvin market? A. I can't remember that specifically. I remember a discussion with Richard Ulmer which he had had with Dennis Dyer, and it was some discussion as to whether this might be a suitable area for us to get into.

And off the top of my head, and in a rather informal discussion, I felt that it was not.

Q. When was this discussiin? A. I can't recall exactly. It was sometime ago.

Q. Why did you consider it not an area to get into? A. Well, two basic reasons. One of them is it was already on the market by two or three companies, and it had been on the market for some time. And as far as I was concerned, it didn't look as though it were a suitable market for us to get into.

Q. What was the other factor? A. What?

Q. Did you say there were two factors?

MR. SAILER: No, I didn't understand him to say there were two factors.

BY MR. WALLACE:

Q. Were you aware that Mr. Ulmer was conducting [p. 8] a market survey relating to Griseofulvin? A. In retrospect, after looking at the documents which, you know, came up just before this, I remember seeing the memo from Dennis Dyer to Rich.

Q. Is that the memo identified as GX-19? A. GX-19, yes.

Q. When did you first see this memo? A. Oh, I don't remember exactly. I know it's dated January 30th, and I probably saw it within two weeks of its issue date.

Q. Did you communicate with Mr. Ulmer in any way respecting Mr. Dyer's request for a market survey? A. I think this is probably the result of our back and forth conversation I mentioned earlier. As far as I was con-

cerned, this memo was a little bit too, or he was asking for more than I felt was necessary. And I can't remember specifically whether I told Rich to go ahead on it or not to go ahead on it. I think, and this is a recollection, that I said maybe you ought to do something less than what he's asking for because I think we could get some idea as to whether this would be a suitable thing to go ahead with or not by a relatively small look at this.

Q. You did not direct him not to conduct the market survey? A. To my recollection, no.

MR. SAILER: By him, you mean Mr. Ulmer?

[p. 9] THE WITNESS: This is what he meant.

BY MR. WALLACE:

Q. Is that your understanding? A. That is my understanding.

Q. I direct your attention to the document which is a four-page document labeled GX-20 through GX-23, which appears to be Mr. Ulmer's market research report. A. Yes.

Q. Have you seen this document before? A. Yes, I have.

Q. When did you first see this document? A. Again I would say I saw it within a week or two weeks after the issue date, May 7.

Q. Did you discuss this document with Mr. Ulmer? A. At the time, no.

Q. Have you discussed it with him since? A. Well, very briefly. Let's say within the last week.

Q. Did you discuss this document with any of the individuals listed on the distribution list of this document? A. Not to my knowledege, no. I think, if I may add, that the document in terms of what it says agreed somewhat with my earlier discussion on what I thought of this particular market for this product.

[p. 10] Q. Were you aware that the Priority Committee decided against marketing Griseofulvin in approximately January of 1968? A. I was aware of it, but I am not sure when, exactly; whether it was January or somewhat later. My whole recollection in this was that Griseofulvin was somewhat laid to rest sometime ago, as far as we were concerned. And if you'll notice the various dates, I was somewhat surprised that there was any real mention of it in this particular thing. The project was sort of cooking

along on a very, very low basis. This report came quite a bit after the initial memo. And as many things, why, you assume some things, you know, have dropped by the wayside, and sometimes they turn up.

MR. MCCANN: As a point of clarification, with your permission——

When you say, "The project was cooking along relatively slow," you are referring to the Market Research project?

THE WITNESS: Right, the Market Research project.

MR. MCCANN: Not any development?

THE WITNESS: Not Griseofulvin per se.

MR. MCCANN: All right.

BY MR. WALLACE:

Q. Were you aware of any documents in your company's possession or documents which have been in your com-

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EXCERPT FROM DEPOSITION OF GALVIN HERBERT, JR., TAKEN JUNE 24, 1968, FILED SEPT. 13, 1968

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[p. 10] BY MR. WALLACE:

Q. My question was when Mr. Herbert, Jr. first heard of Griseofulvin. There's been several articles in the Pink sheet on Griseofulvin. A. When I first heard of Griseofulvin? The answer to that is I suppose it would be 10 years ago or 15 years ago, whenever it first came out; just as a matter of general interest in regards to all kinds of companies.

Q. To your knowledge, when was Griseofulvin first considered by anyone in your corporation as a new product? A. Well, it was apparently around November or December, to the best of my knowledge.

MR. SAILER: Of 1967?

THE WITNESS: Yes, the end of last year. And it came before the Priority Committee. It was given about three minutes' consideration, and that was the end of it.

BY MR. WALLACE:

Q. How did it come before the Priority Committee?

A. Well, at each meeting Dr. Nelson would have a list of new projects that he wished to be considered. In other words, we have X amount of research time, and if that time is being utilized with current projects, then we must bump a current project to allow a new compound to come in. And we simply didn't have any interest in the compound.

Q. What were the reasons for not having an [p. 11] interest in the compound? A. Lack of research time, and just general lack of interest. I mean, it's a kind of rather arbitrary decision that I personally had no interest in because, frankly, from what I had heard, I didn't think it would work.

Q. You didn't think what would work?

A. Well, the topical Griseofulvin would work. There's no evidence to suggest it would, and I didn't feel that in view of the new drug application, this would apply to new drug application, which would require the expenditure of a quarter to a half million dollars, and I did not fool, based on what was in the literature, or that which I was aware of in the past that it would work, and we were not in a position to take those kinds of risks. We just weren't interested.

Q. Who proposed the topical Griseofulvin? A. I believe Dr. Nelson brought it up, and I can't recall. It must have been Dr. Nelson. That would be his responsibility.

Q. Have you seen any documents that discuss a topical application of Griseofulvin? A. I saw some internal documents after I became aware of all of this, the same ones that are on file here. I had not seen that document, even though my name is on the circulation list.

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EXCERPT FROM DEPOSITION OF ERIC L. NELSON, TAKEN JUNE 24, 1968, FILED SEPT. 13, 1968

* * * * *

[p. 6] A. Until recently, Director of Project Development. Now he also has a joint employment as Manager of Dermatology or something like that.

MR. MCCANN: Yes.

THE WITNESS: Manager of Dermatology Division.

BY MR. WALLACE:

Q. What is Dr. Erickson's first name? A. Stewart.

Q. What is his position? A. Director of Medical Research.

Q. What is Dr. Shel's first name? A. John.

Q. What is his position? A. He is Director of Health Service Research Institute.

Q. What is Dr. Brabander's first name? A. Wayne.

Q. What is his position? A. He is Director of Quality Control.

Q. When were you first made aware that your company was looking into the possibility of marketing Griseofulvin?

A. I don't believe our company was looking into it.

Q. Are you aware that your company ever considered it?

[p. 7] A. As a company, no. We had a request from one of our people to consider an idea of his, which we considered and sent back a negative on. It happens all the time.

Q. I direct your attention to GX-18. A. Yes.

Q. Have you seen this document before? A. Yes, that "Not available" is my handwriting.

Q. What doees that mean? A. That means that this product is not available for us to consider.

Q. Why? A. Because we had no particular interest in it, either from a marketing standpoint or in terms of our priority.

Q. Was this document the first suggestion to the Priority Committee that Griseofulvin be considered? A. There was a companion document which I can't indicate, which was a request for using this material in a diagnostic media, which was the idea of Mr. Dyer, which was attached to this. And he refers to it here when he's talking about this culture swab.

Q. Griseofulvin containing culture swab? A. That's right.

Q. This was attached to GX-18? A. It was merely a sketch of his idea. This was [p. 8] returned to him with the negative.

Q. Are you aware of any copies of this document? A. No, there were no copies.

Q. What happened to it? A. It went back to him, and as I understand, he destroyed it.

Q. When did the Priority Committee consider the Griseofulvin proposal? A. Well, that was probably about the first week or so in January.

Q. Was it at a meeting? A. No. It was informal discus-

sions probably at a time when we were together for some other reason.

Q. With the other members of the Priority Committee? A. Yes.

Q. Who were they? A. Mr. Herbert, who really is the ultimate decision, and Mr. Evans, who is the Sales Manager.

Q. Is that Mr. Herbert, Jr.? A. Junior, and myself.

Q. How long did the discussion respecting Griseofulvin last? A. Well, if it lasted over a minute, I suppose it was too much.

Q. What was said?

[p. 9] A. I can't remember, other than we weren't interested.

Q. Are you aware of any other documents relating to Griseofulvin? A. This other one you have here that showed up more recently.

Q. Referring to GX-20? A. Yes.

Q. Through 23? A. 20, I guess it is.

Q. The pages are numbered 20 through 23. A. Yes.

Q. Have you seen this document before? A. Yes.

Q. When was the first time you saw this? A. Let's see the date on it. I probably saw it sometime within the following week.

Q. Did you take any action in response to this document? A. I was frankly surprised to see it because I thought we had forgotten about it. However, some of the information on here, I suppose was pertinent to a general consideration of the fungicide field.

Q. Are you aware of any document from the Priority Committee to Mr. Dyer stating that the Griseofulvin proposal had been rejected?

[p. 10] A. Yes, he would get this back.

Q. GX-18? A. Yes, with his attached. That is why we don't have it.

Q. Did he get any other communications? A. No.

Q. Does the Priority Committee normally send communications out with the instructions "Read and discard"? A. Everything that goes out of that meeting, except for the final copy, usually has that connotation on it.

Q. Is the final copy of every document kept? A. Everything like this, that we keep. That is why we have this one.

Q. Are you aware of any communications between your company—strike that question.

Are you aware of any documents in the possession of your company or that have been in the possession of your company other than the documents which were produced in response to the Government's subpoena which relates to Griseofulvin? A. Would you care to say that again?

Q. Are you aware of any document in the possession of your company or which have been in the possession of your company which relate to Griseofulvin, which has not been produced in response to the Government's subpoena?

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EXCERPTS FROM DEPOSITION OF MARLIN T. LEFFLER, TAKEN OCT. 19, 1968, FILED DEC. 5, 1968

* * * * *

[p. 9] Manufacture chemical products for other companies? A. Certain chemical products that would be within our capabilities, yes.

Q. Would Griseofulvin be one of those products? A. Yes.

Q. Who would have made the final decision at Johnson and Johnson that requested you to manufacture Griseofulvin for them? A. As to whether we would do it?

Q. As to whether you would or would not do it. A. I can't answer that. Do you want me to make a guess?

Q. Well, as a general—your general way of operating in 1958 and '59, if an order came in with a request for manufacturing of a certain chemical, what would be the normal routine in deciding whether or not to manufacture such chemical? A. Well, first, it would be necessary to determine if we needed to have a license to manufacture, and then that would be processed by the licensing department, and then I suppose that the marketing division, the chemical marketing division, who would be responsible for the sale of the bulk material, would have to decide whether they really wanted to [p. 10] get into that business. So this would have brought Mr. Thayer into the picture.

Q. Well, do I understand you correctly, you would act sort of as overall coordinator of such a project? A. No. I would merely initiate the first research inquiry, and, of course, this is the reason that I got in touch with Mr. Lycan, who was in the research division of Johnson and Johnson.

Q. I direct your attention, Dr. Leffler, to GX 49, which

appears to be a letter dictated by M. N. Scorgie to you, dated 15 December, 1959. Do you recall receiving this letter? A. Yes.

Q. Would you identify the pencilled notations which appear on this letter? A. They read "Any added comments? Should we drop?"

Q. Who wrote that? A. I did.

Q. Who was it directed to? A. Dr. Sylvester.

Q. Is that his name at the top of the page? A. Yes, the handwritten—the signature—I mean the name, is that the one you are referring to?

* * * * *

[p. 21] CROSS EXAMINATION

BY MR. SAILER:

Q. Dr. Leffler, did Mr. Scorgie's responsibilities relate solely to the English market? A. Yes.

Q. Drawing your attention to GX 90, is that a very unusual kind of letter to come out of Abbott Laboratories to another chemical company? A. It is very usual.

Q. And——

MR. WALLACE: Excuse me, did you say "usual"?

THE WITNESS: It is very usual; it is commonly done.

BY MR. SAILER:

Q. And is it fair to say that the great majority of those letters do not result in any sort of a deal or relationship of any kind? A. The majority?

Q. Yes. A. Yes.

Q. The majority do not? A. Do not.

Q. Now, drawing your attention to GX 45. At the time of that letter, in connection with that [p. 22] letter, were you considering, with respect to Griseofulvin, anything more than the possible manufacture of it in bulk for a particular customer, Johnson and Johnson, is that what you were considering then? A. I?

Q. Yes. A. That's all.

Q. And that is what that letter is related to, is that right? A. Yes.

Q. Now, I call your attention to GX 51, which is a memorandum from F.J.K., who would be? A. Frederick J. Kirchmeyer.

Q. To. Dr. A. W. Weston, which says, does it not, in substance, that given the state of the market and the number of competitors in the United States he didn't believe it would be wise to pursue Griseofulvin? A. That is my understanding.

Q. Did you agree with that conclusion at that time? A. Did I agree with it?

Q. Yes, sir.

[p. 23] A. Well, that was outside my bailiwick.

Q. I draw your attention to GX 55, a copy of which is shown as having gone to you, and particularly to the third paragraph where it is stated by Mr. Kirchmeyer "I doubt whether we could ever successfully market Griseofulvin when you consider the size of the market and the number of people who already market it," did you have any opinion on that subject at that time? A. Well, as a research man, I might have had an opinion, but it wouldn't have really been one that I would use in helping the company make a decision, because it is outside of my area.

Q. This is not within your responsibility? A. No, no.

Q. Now, I would like to draw your attention to GX 79 and 80, and ask you whether the subject matter discussed in those documents is also beyond your bailiwick or responsibilities? A. May I take a minute to read these?

Q. Certainly. A. (Examining documents.) This material is outside of my responsibility.

Q. Now, GX 80 shows that a copy went to you,

* * * * *

[p. 30] obtained?

A. No. It is one of the ways. I don't know that you can say that it is the usual way.

Q. Is it one of the more direct ways that are used to obtain new products? A. Quite often the technical people, because they are most knowledgeable at the time in the new products that have been developed, will get in touch with the technical people and the original source.

Q. With reference to GX 90, do you know of any reason that Dr. Baker would have sent this letter to Glaxo Laboratories Limited, other than the possibility of obtaining a new product for Abbott Laboratories?

MR. TIMBERG: I think I must object to this as calling for a reason in Dr. Baker's mind.

MR. WALLACE: I am asking——

MR. TIMBERG: I think you have been told where Dr. Baker is now located.

MR. WALLACE: I am trying to shorten this. I am not going to Ohio for another deposition.

MR. TIMBERG: Good.

BY MR. WALLACE:

Q. Do you know of any reason Dr. Baker would [p. 31] have written this letter to Glaxo Laboratories, GX 90, other than the possibility of obtaining a new product for Abbott Laboratories? A. I know of no other reason.

Q. Dr. Leffler, you testified on cross examination that the majority of the letters of the type of GX 90 do not result in new products.

Does Abbott Laboratories still at this present date send out letters of the type of GX 90 requesting information on the possibilities of new products? A. Yes, occasionally.

Q. Do the majority of them still not result in new products? A. Yes.

Q. Why do you continue to send them out? A. Because once in awhile they work.

Q. Dr. Leffler, does Abbott Laboratories presently manufacture bulk chemicals for sale to other drug companies? A. Yes.

Q. Is it frequently the case that when you manufacture bulk chemicals for other companies you will sell such bulk chemicals to more than one drug company?

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EXCERPT FROM DEPOSITION OF BRUCE K. ROSS, TAKEN OCT. 19, 1968, FILED DEC. 5, 1968

* * * * *

[p. 19] BY MR. WALLACE:

Q. Why do you say Griseofulvin would not have been considered by the new products committee? A. Because my understanding of the things that come before the new products committee is the marketing of pharmaceutical dosage forms, I do not believe that the question of manufacturing of bulk material would—and the sale of a bulk chemical would come before it, and furthermore, as far as the pharmaceutical dosage form application here, this material to me indicates that we did a rather cursory investi-

gation of the market for pharmaceutical dosage forms and concluded that we had no interest; so it would not be something that would clutter the agenda of the new products committee.

Q. If Dr. R. F. Baker of the Veterinary Department had proposed a veterinary product for the treatment of mange, would that have been considered by the new products committee? A. It is possible it could, if it passed certain preliminary screening programs.

Q. That is within the scope of the—— A. Yes, it would be.

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ABBOTT DEPOSITION EXHIBIT 51

Dr. A. W. Weston, D-430

January 14, 1960

In regard to the attached, I do not belive that we would be wise in pursuing Griseofulvin.

As you probably know, three companies are now marketing Griseofulvin in the United States, all of it imported from England. When the last of the three introduced their brand of Griseofulvin into the market the other two cut their prices 20% and it appears that even stiffer competition is in the offing.

FJK:kh

ABBOTT DEPOSITION EXHIBIT 80

December 6, 1962

Mr. W. Behrens, D-590
cc: Mr. F. J. Kirchmeyer, D-402
Mr. R. Nichols, D-309 Dr. E. J. Matson, D-410
Mr. N. Leffler, D-902 File (I)

Re: *Griseofulvin* (*McNeil Laboratories*)

Pursuant to your request that we look into the advisability of manufacturing Griseofulvin for McNeil Laboratories, we have reviewed the past history of Abbott's interest in Griseofulvin, the patent situation, McNeil's requirements and the domestic pharmaceutical market picture and have concluded that we should inform McNeil that we are not interested.

In the first place, the patent situation is quite clear. Glaxo has the process patents cornered and it would be necessary to obtain a license from them to manufacture. They have been reluctant to grant such licenses to the other firms in

the U.S. who sell Griseofulvin, apparently preferring to sell the bulk material to these firms themselves. I understand that we tried previously to get such a license (for Abbott England, I think) and were unsuccessful.

As a product possibility for the domestic pharmaceutical market, we cannot find a great deal of interest. The market is not particularly large and there are at least four firms established in this market (Ayerst, McNeil, Orthe Division of Johnson & Johnson, and Schering) and the market was down 10% over the previous year until several new variations were introduced by several of the firms. Probably the only thing which would be in it for us would be whatever we could pick up on manufacture for McNeil. Their requirements have been estimated at $300-360,000 a year. Although we do not know what the after-tax profits would be, it probably isn't too attractive a project, considering the development costs which would be required.

I do not believe Glaxo would grant us a license to manufacture and sell because this would jeopardize their position as supplier of the bulk material to their customer-licensees, such as McNeil. I think it would be just time and effort wasted to approach Glaxo.

Our recommendation is that Chemical Marketing (or whoever was the original McNeil contact on this) write to McNeil to inform them that we are not interested. Please let me know if you want the file material returned to you. If not, I will keep it with the rest of our file.

ORDER OF UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT, FILED JUNE 25, 1968

No. Misc. 3261
Glaxo Group Limited,
Applicant,
v.
United States of America,
Respondent.

Before: Bazelon, Chief Judge; and Burger and Robinson, Circuit Judges, in Chambers.

On consideration of applicant's application for permission to appeal, of respondent's opposition thereto and applicant's reply, it is

ORDERED by the Court that applicant's aforesaid application is denied. *Brown Shoe Co.* v. *United States,* 370 U.S. 294, 305 n. 9 (1962); *United States* v. *California Co-operative Canneries,* 279 U.S. 461 (1929); *National Association of Real Estate Boards* v. *United States,* 85 U.S. App. D.C. 165, 176 F.2d 631 (1949).

Per Curiam.

Circuit Judge Burger did not participate in the foregoing order.

ORDER OF DISTRICT COURT, FILED JULY 24, 1969, DENYING PLAINTIFF'S OCTOBER 30, 1968, CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT THAT THE ICI PATENT IS INVALID

[Caption Omitted]

Upon consideration of the June 4, 1969, ruling of this Court that plaintiff is without standing to challenge the validity of the ICI patent, it is this 24 day of July, 1969, hereby

ORDERED that plaintiff's October 30, 1968, Cross-Motion for Partial Summary Judgment that the ICI patent is invalid be denied.

/s/ Oliver Gasch
United States District Court

SUPREME COURT OF THE UNITED STATES

No. 71-666

UNITED STATES,
APPELLANT,

v.

GLAXO GROUP LIMITED, ET AL.

APPEAL from the United States District Court for the District of Columbia.

The statement of jurisdiction in this case having been submitted and considered by the Court, probable jurisdiction is noted.

February 22, 1972

ORDER FILED MARCH 21, 1972, AMENDING FINAL JUDGMENT

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Filed March 21, 1971, James F. Davey, Clerk

UNITED STATES OF AMERICA, PLAINTIFF, v. GLAXO GROUP LIMITED, ET AL., DEFENDANTS.	Civil Action No. 558-68

ORDER

It is hereby ORDERED, ADJUDGED and DECREED, with the consent of counsel, that the Final Judgment herein entered June 17, 1971, shall be, and the same hereby is, amended by substituting for Article V thereof the following:

"V.

"Defendant Glaxo is prohibited from transferring any assets subject to this Final Judgment, other than goods sold or otherwise transferred in the ordinary course of business, to any third party ("Takeover Party") that at such time, to Glaxo's knowledge, proposes to make or has extant any tender offer or takeover bid in respect to the stock or assets of Glaxo, or has acquired such stock or assets or has entered into any merger with Glaxo or agreement therefor, or any affiliate thereof, or to any person acting in concert with or on behalf of any of the foregoing; and Glaxo is also prohibited from failing to engage in any activity subject to this Final Judgment in order that the Takeover Party, or any affiliate thereof, or any person acting in concert with or on behalf of any of the foregoing, may engage in such activity in lieu of Glaxo, unless the Takeover Party, affiliate, or person acting in concert therewith or on its behalf, shall first have submitted to the jurisdiction of the Court in this proceeding and consented to be bound by this Final Judgment to the extent provided by law, provided, that Glaxo shall be free to take any action referred to above, if after 30 days' prior notice to plaintiff

of its intent to do so plaintiff has not filed with this Court any objection, and provided further that if plaintiff has filed any such objection Glaxo shall not take such action until (a) the Takeover Party, affiliate, or person acting in concert therewith or on behalf thereof has submitted to the jurisdiction of the Court in this proceeding and has consented to be bound by this Final Judgment to the extent provided by law, or (b) the Court shall have ruled that Glaxo may take such action without such submission."

It is FURTHER ORDERED that Articles V through VIII of said Final Judgment shall be, and the same hereby are, renumbered as Articles VI through IX.

/s/ OLIVER GASCH
Judge

Date: March 9, 1972

☆ U.S. Government Printing Office: 1972—463-272/666